Healthcare Regulation Subcommittee

Thursday, February 1, 2024
11:30 AM
Reed Hall (102 HOB)

Meeting Packet

Paul Renner
Speaker

Michelle Salzman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Healthcare Regulation Subcommittee

Start Date and Time: Thursday, February 01, 2024 11:30 am

End Date and Time: Thursday, February 01, 2024 02:30 pm

Location: Reed Hall (102 HOB)

Duration: 3.00 hrs

Consideration of the following bill(s):

HB 159 HIV Infection Prevention Drugs by Franklin
HB 255 Psychiatric Treatments by Amesty
HB 493 Pharmacy by Roach
HB 499 Congenital Cytomegalovirus Screenings by Melo
HB 547 Dentistry by Altman
HB 1269 Potency for Adult Personal Use of Marijuana by Massullo, Fine
HB 1295 Health Care Practitioner Titles and Abbreviations by Massullo
HB 1313 Clinical Laboratory Personnel by Chamberlin
HB 1405 Acupuncture by Altman
HB 1435 Medical Marijuana Use Registry Identification Cards for Veterans by Valdés

Consideration of the following proposed committee substitute(s):

PCS for HB 349 -- Sickle Cell Management and Treatment Education for Physicians

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m. Wednesday, January 31, 2024.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Wednesday, January 31, 2024.

To submit an electronic appearance form, and for information about attending or testifying at a committee meeting, please see the "Visiting the House" tab at www.myfloridahouse.gov.

NOTICE FINALIZED on 01/30/2024 3:43PM by Arnold.Sabrina

HB 159

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 159 HIV Infection Prevention Drugs
SPONSOR(S): Franklin
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Pharmacy is the third largest health profession in the US, following only nursing and medicine. In Florida, the Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacy. Pharmacist's scope of practice includes the compounding, dispensing, and consulting of patients concerning contents, therapeutic values, and uses of a medicinal drug.

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. If not properly treated, HIV can lead to fatal acquired immunodeficiency syndrome (AIDS). According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million people in the United States currently living with HIV.

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are two biomedical prevention strategies for people without HIV. PrEP is taken before HIV exposure and for people who do not have HIV but are at a high risk of exposure to HIV, PrEP can be used to significantly reduce risk of HIV infection. PrEP is available in two forms: a daily oral medication and a long-acting injectable delivered once every two months. PEP is taken after a person has been exposed to HIV. PEP is intended for use in emergency situations, and is not meant for frequent use by people who are at high risk of HIV exposure. When taken within 72 hours of HIV exposure, PEP significantly reduces risk of HIV infection.

HB 159 establishes two processes under which a certified pharmacist may be authorized to screen for HIV exposure and order and dispense HIV infection prevention drugs. The bill allows certified pharmacists to screen for HIV exposure and order and dispense HIV infection prevention drugs in accordance with a written protocol between the pharmacist and a supervising physician. The bill also authorizes the BOP, in conjunction with the Board of Medicine and Board of Osteopathic Medicine, to develop a statewide drug therapy protocol under which a certified pharmacist may order and dispense HIV infection prevention drugs.

The bill creates a certification and establishes minimum criteria for the certification which a pharmacist must obtain before they may order and dispense HIV infection prevention drugs.

The bill directs the BOP to develop rules to implement the provisions of the bill.

The bill has an insignificant, negative fiscal impact on DOH, and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Pharmacist Licensure and Regulation

Pharmacy is the third largest health profession in the US, following only nursing and medicine.[1] The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S. To be licensed as a pharmacist, a person must:[2]

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;[3]
- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

A pharmacist must complete at least 30 hours of Board-approved continuing education during each biennial renewal period.[4] Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a 3-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.[5] Pharmacists who administer long-acting antipsychotic medications must complete an approved 8-hour continuing education course as a part of the continuing education for biennial licensure renewal.[6] All pharmacists are required to complete a 1-hour continuing education course on HIV/AIDS as a part of their first licensure renewal.[7]

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:[8]

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[9]
- Administering epinephrine injections;[10] and

[1] American Association of Colleges of Pharmacy, *About AACP*. Available at https://www.aacp.org/about-aacp (last visited January 31, 2024).
[2] S. 465.007, F.S.
[3] If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist
[4] S. 465.009, F.S.
[5] S. 465.009(6), F.S.
[6] S. 465.1893, F.S.
[7] See, Board of Pharmacy, *Pharmacist: Continuing Education Requirements*. Available at https://floridaspharmacy.gov/renewals/pharmacist/#tab-ce (last visited January 31, 2024).
[8] S. 465.003(13), F.S.
[9] *See* s. 465.189, F.S.
[10] *Id*.

- Administering antipsychotic medications by injection.[11]

A pharmacist may not alter a prescriber's directions, diagnose or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.[12]

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Board of Medicine, the Board of Osteopathic Medicine, and the BOP. The formulary may only include:[13]

- Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);
- Any medicinal drug recommended by the FDA Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination;
- Any medicinal drug containing fluoride in any strength;
- Any medicinal drug containing lindane in any strength;
- Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program; and
- Any topical anti-infectives, excluding eye and ear topical anti-infectives

A pharmacist may order the following, within his or her professional judgment and subject to the conditions established by rule:[14]

- Certain oral analgesics for mild to moderate pain. The prescription is limited to a six-day supply for one treatment of:
    - Magnesium salicylate/phenyltoloxamine citrate.
    - Acetylsalicylic acid (Zero order release, long acting tablets).
    - Choline salicylate and magnesium salicylate.
    - Naproxen sodium.
    - Naproxen.
    - Ibuprofen.
- Certain urinary analgesics, not exceeding a two (2) day supply;
- Otic analgesics. Antipyrine 5.4%, benzocaine 1.4%, glycerin, if clinical signs or symptoms of tympanic membrane perforation do not exist. The product shall be labeled for use in the ear only;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal;/antibacterial treatments;
- Topical anti-inflammatory treatments;
- Certain otic antifungal/antibacterial treatments.
- Keratolytics for the treatment of warts, except in patients under age two, or with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid in excess of 0.9 mg;
- Medicinal shampoos containing lindane for the treatment of head lice;
- Certain ophthalmic solutions;
- Certain histamine H12 antagonists;
- Certain acne products; and
- Topical antiviral to treat herpes simplex infections of the lips.

Human Immunodeficiency Virus

[11] S. 465.1893, F.S.
[12] S. 465.003, F.S.
[13] S. 456.186, F.S.
[14] Rule 64B16-27.220, F.A.C.

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. If not properly treated, HIV can lead to acquired immunodeficiency syndrome (AIDS), the third and most severe stage of HIV infection. Without proper treatment, people with AIDS typically survive about three years.[15]

There is currently no effective cure for HIV. Once a person has HIV, they have it for life.[16] The symptoms and transmission of HIV can be mitigated through medication. When HIV is controlled through medication, the risk of transmission is close to zero. People who have HIV and are not on medication and do not have consistent control of their HIV can transmit the virus through sex, sharing of needles used for IV drug use, pregnancy, and breastfeeding.[17]

A person can mitigate their risk of contracting HIV through various prevention strategies. Using condoms correctly during every sexual encounter, not using intravenous drugs, and if you do, using clean needles significantly reduce one's risk for contracting HIV. For pregnant women with HIV, taking the appropriate HIV medication reduces the change of transmitting HIV to the infant to less than one percent.[18]

According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million people in the United States currently living with HIV.[19] HIV disproportionately impacts certain segments of the US population, particularly those who live in the Southern US, including Black and Hispanic Americans, men who have sex with men, transgender people, people who use drugs, and rural communities.[20]

PrEP and PEP

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are two biomedical prevention strategies for people without HIV. "Prophylaxis" means to prevent or control the spread of an infection of disease, and pre- and post-exposure refers to when the treatment is taken in relation to HIV exposure.

PrEP is taken before HIV exposure and for people who do not have HIV but are at a high risk of exposure to HIV, PrEP can be used to significantly reduce risk of contracting HIV. A person may have a high risk of exposure to HIV through sex with a partner who is HIV-positive or through IV drug use. PrEP is available in two forms: a daily oral medication and a long-acting injectable delivered once every two months. Studies have shown that consistent use of PrEP reduces the risk of contracting HIV from sex by approximately 99 percent, and from IV drug use by at least 74 percent.[21]

PEP is a medication that is taken soon after exposure to HIV to prevent HIV infection in people who are HIV negative or do not know their HIV status. PEP must be taken within 72 hours of exposure, and should be taken as soon after exposure as possible. PEP is intended for use in emergency situations,

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[15] Centers for Disease Control and Prevention, *About HIV*. Available at https://www.cdc.gov/hiv/basics/whatishiv.html (last visited January 31, 2024).
[16] *Id*.
[17] National Institutes of Health (NIH), HIV and AIDS: The Basics (2023). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-and-aids-basics (last visited January 31, 2024).
[18] National Institutes of Health (NIH), *The Basics of HIV Prevention* (2023). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/basics-hiv-prevention (last visited January 31, 2024).
[19] Centers for Disease Control and Prevention, *HIV Surveillance Report: Estimated HIV Incidence and Prevalence in the United States, 2015-2019* (2021). Available at https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf (last visited January 31, 2024).
[20] Centers for Disease Control and Prevention, *HIV Surveillance Report: Diagnoses of HIV Infection in the United States and Dependent Areas, 2021* (2023). Available at https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/index.html (last visited January 31, 2024). For more information on the growing prevalence of HIV in rural communities, *see*, Schafer, et al., *The Continuum of HIV Care in Rural Communities in the United States and Canada: What Is Known and Future Research Directions* (2019). Journal of Acquired Immune Deficiency Syndrome, 75(1): 35-44. doi: 10.1097/QAI.0000000000001329
[21] National Institutes of Health (NIH), *Pre-Exposure Prophylaxis (PrEP)* (2023). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/pre-exposure-prophylaxis-prep (last visited January 31, 2024).

and is not meant for frequent use by people who are at high risk of HIV exposure. PEP is taken for 28 days following HIV exposure.[22]

PEP may be prescribed to someone who, in the last 72 hours:[23]

- May have been exposed to HIV during sex;
- Shared needles or other equipment to inject drugs;
- Were sexually assaulted; or
- May have been exposed to HIV at work.[24]

PEP is the only HIV prevention method that can be taken after exposure to HIV. When taken within 72 hours of exposure, PEP is estimated to be more than 90 percent effective.[25]

Currently, at least 12 states have passed legislation allowing pharmacists to directly administer either PrEP or PEP to patients under certain circumstances.[26]

Effect of the Bill

HB 159 establishes two processes under which a certified pharmacist may be authorized to screen for HIV exposure and order and dispense HIV Infection prevention drugs. The bill defines HIV infection prevention drugs as pre-exposure prophylaxis and post-exposure prophylaxis, and any other drug approved by the US Food & Drug Administration for the prevention of HIV infection.

The bill requires a pharmacist to be certified by the BOP before they may order and dispense HIV infection prevention drugs. The BOP, in conjunction with the Board of Medicine and Board of Osteopathic Medicine, must adopt rules for the certification. To be certified, a pharmacist must, at a minimum:

- Hold an active and unencumbered license to practice pharmacy;
- Be engaged in the active practice of pharmacy;
- Have earned a doctorate of pharmacy degree or have completed at least 5 years of experience as a licensed pharmacist;
- Maintain at least $250,000 of liability coverage;[27] and
- Have completed a course approved by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, which includes, at a minimum, instruction on all of the following:
    - Performance of patient assessments;
    - Point-of-care testing procedures;
    - Safe and effective treatment of HIV exposure with HIV infection prevention drugs; and
    - Identification of contraindications.

Under the bill, certified pharmacist may screen for HIV exposure and order and dispense HIV infection prevention drugs in accordance with a written protocol between a pharmacist and a supervising physician.

The bill also authorizes the BOP, in conjunction with the Board of Medicine and Board of Osteopathic medicine, to develop a statewide drug therapy protocol for pharmacists to test or screen for HIV exposure and order and dispense HIV infection prevention drugs. Pharmacists ordering and dispensing HIV infection

[22] National Institutes of Health (NIH), *Post-Exposure Prophylaxis (PEP)* (2021). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/post-exposure-prophylaxis-pep (last visited January 31, 2024).
[23] *Id*.
[24] Occupational exposure to HIV is very rare. For more information, see, Centers for Disease Control and Prevention, *HIV and Occupational Exposure* (2019). Available at https://www.cdc.gov/hiv/workplace/healthcareworkers.html (last visited January 31, 2024).
[25] Ayieko, J., Petersen, M. L., Kamya, M. R., & Havlir, D. V., *PEP for HIV prevention: are we missing opportunities to reduce new infections?* (2022). Journal of the International AIDS Society, 25(5), e25942. https://doi.org/10.1002/jia2.25942
[26] The states include Arkansas, California, Colorado, Illinois, Maine, Nevada, New Mexico, North Carolina, Oregon, Utah, and Virginia. *See*, NASTAD, *Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements*. (2023). Available at https://nastad.org/sites/default/files/2023-08/PDF-Pharmacist-Authority-Initiate-PrEP-PEP.pdf (last visited January 31, 2024).
[27] A pharmacist who maintains liability coverage pursuant to ss. 465.1865 or 465.1895, F.S. satisfies this requirement.

prevention drugs under this provision must be certified, but would not necessarily be required to operate under physician supervision. In developing a statewide drug therapy protocol, the BOP must consider, at a minimum, all of the following:

- Physician referrals;
- Lab testing, including prescribing HIV preexposure and postexposure screening tests;
- Appropriate referrals consistent with guidelines of the United States Centers for Disease Control and Prevention;
- Counseling consistent with guidelines of the United States Centers for Disease Control and Prevention; and
- Patient follow-up care and counseling.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:
Section 1: Creates s. 465.1861, F.S., relating to ordering and dispensing HIV infection prevention drugs.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:
None.

2. Expenditures:
The bill has an insignificant negative fiscal impact on DOH that can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
None.

2. Expenditures:
None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:
None.

D. FISCAL COMMENTS:
None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:
Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:
None.

B. RULE-MAKING AUTHORITY:
The bill provides sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:
None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to HIV infection prevention drugs; creating s. 465.1861, F.S.; defining terms; authorizing licensed pharmacists to screen for HIV exposure and order and dispense HIV infection prevention drugs in accordance with a certain written supervisory protocol or statewide drug therapy protocol; requiring pharmacists to be certified by the Board of Pharmacy before ordering and dispensing HIV infection prevention drugs; requiring the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules for such certification; specifying minimum requirements for the certification; requiring the board, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, and the Department of Health, to develop a certain statewide drug therapy protocol; providing requirements for development of the protocol; requiring the board to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 465.1861, Florida Statutes, is created to read:

465.1861 Ordering and dispensing HIV infection prevention drugs.—

(1) As used in this section, the term:

(a) "HIV" means the human immunodeficiency virus.

(b) "HIV infection prevention drug" means preexposure prophylaxis, postexposure prophylaxis, and any other drug approved by the United States Food and Drug Administration for the prevention of HIV infection.

(c) "Postexposure prophylaxis" means a drug or drug combination that meets the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral treatment following potential exposure to HIV.

(d) "Preexposure prophylaxis" means a drug or drug combination that meets the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral treatment for the prevention of HIV transmission.

(2) A pharmacist may screen for HIV exposure and order and dispense HIV infection prevention drugs in accordance with a written protocol between the pharmacist and a supervising physician or a statewide drug therapy protocol developed pursuant to subsection (4).

(3) Before ordering or dispensing HIV infection prevention drugs under this section, a pharmacist must be certified by the

board, according to the rules adopted by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine. To be certified, a pharmacist must, at a minimum, meet all of the following criteria:

(a) Hold an active and unencumbered license to practice pharmacy under this chapter.

(b) Be engaged in the active practice of pharmacy.

(c) Have earned a doctorate of pharmacy degree or have completed at least 5 years of experience as a licensed pharmacist.

(d) Maintain at least $250,000 of liability coverage. A pharmacist who maintains liability coverage pursuant to s. 465.1865 or s. 465.1895 satisfies this requirement.

(e) Have completed a course approved by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, which includes, at a minimum, instruction on all of the following:

1. Performance of patient assessments.

2. Point-of-care testing procedures.

3. Safe and effective treatment of HIV exposure with HIV infection prevention drugs.

4. Identification of contraindications.

(4) The board, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, and the department, shall develop a statewide drug therapy protocol for pharmacists to

test or screen for HIV exposure and order and dispense HIV infection prevention drugs. In development of the statewide drug therapy protocol, the board must consider, at a minimum, all of the following:

(a) Physician referrals.

(b) Lab testing, including prescribing HIV preexposure and postexposure screening tests.

(c) Appropriate referrals consistent with guidelines of the United States Centers for Disease Control and Prevention.

(d) Counseling consistent with guidelines of the United States Centers for Disease Control and Prevention.

(e) Patient follow-up care and counseling.

(5) The board shall adopt rules to implement this section, including rules that establish protocols for ordering and dispensing HIV infection prevention drugs.

Section 2. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Franklin offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 465.1861, Florida Statutes, is created to read:

465.1861 Ordering and dispensing HIV infection prevention drugs.--

(1) As used in this section, the term:

(a) "HIV" means the human immunodeficiency virus.

(b) "HIV infection prevention drug" means preexposure prophylaxis, postexposure prophylaxis, and any other drug approved by the United States Food and Drug Administration for the prevention of HIV infection.

(c) "Postexposure prophylaxis" means a drug or drug combination that meets the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral treatment following potential exposure to HIV.

(d) "Preexposure prophylaxis" means a drug or drug combination that meets the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral treatment for the prevention of HIV transmission.

(2) A pharmacist may screen an adult for HIV exposure and provide the results to that adult, with the advice that the patient should seek further medical consultation or treatment from a physician.

(3) A pharmacist may dispense HIV preexposure prophylaxis drugs pursuant to a valid prescription issued by a licensed health care practitioner authorized by law to prescribe such drugs.

(4) A pharmacist who is certified under subsection (6) may order and dispense HIV postexposure prophylaxis drugs pursuant to a written collaborative practice agreement between the pharmacist and a physician licensed under chapter 458 or chapter 459.

(a) A written collaborative practice agreement between a pharmacist and a physician under this section must include, at a minimum, all of the following:

1. Terms and conditions relating to the screening for HIV and the ordering and dispensing of HIV postexposure prophylaxis drugs by the pharmacist. Such terms and conditions must be appropriate for the pharmacist’s training.

2. Specific categories of patients the pharmacist is authorized to screen for HIV and for whom the pharmacist may order and dispense HIV postexposure prophylaxis drugs.

3. The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the use of HIV postexposure prophylaxis drugs.

4. A process and schedule for the physician to review the pharmacist's actions under the practice agreement.

5. Evidence of the pharmacists’ current certification by the board as provided in subsection (6).

6. Any other requirements as established by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine.

(b) A physician who has entered into a written collaborative practice agreement pursuant to this section is

responsible for reviewing the pharmacist's actions to ensure compliance with the agreement.

(c) The pharmacist shall submit a copy of the written collaborative practice agreement to the board.

(5) A pharmacist who orders and dispenses HIV postexposure prophylaxis drugs pursuant to subsection (4) must provide the patient with written information advising the patient to seek follow-up care from his or her primary care physician. If the patient indicates that he or she lacks regular access to primary care, the pharmacist must comply with the procedures of the pharmacy's approved access-to-care plan as provided in subsection (6).

(6) To provide services under a collaborative practice agreement pursuant to this section, a pharmacist must be certified by the board, according to rules adopted by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine. To be certified a pharmacist must, at a minimum, meet all of the following criteria:

(a) Hold an active and unencumbered license to practice pharmacy under this chapter.

(b) Be engaged in the active practice of pharmacy.

(c) Have earned a degree of doctor of pharmacy or have completed at least 3 years of experience as a licensed pharmacist.

(d) Maintain at least $250,000 of liability coverage. A pharmacist who maintains liability coverage pursuant to s. 465.1865 or s. 465.1895 satisfies this requirement.

(e) Have completed a course approved by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, which includes, at a minimum, instruction on all of the following:

1. Performance of patient assessments.

2. Point-of-care testing procedures.

3. Safe and effective treatment of HIV exposure with HIV infection prevention drugs, including, but not limited to, consideration of the side effects of the drug dispensed and the patient's diet and activity levels.

4. Identification of contraindications.

5. Identification of patient comorbidities in individuals with HIV requiring further medical evaluation and treatment, including, but not limited to, cardiovascular disease, lung and liver cancer, chronic obstructive lung disease, and diabetes mellitus.

(7) A pharmacy wherein a pharmacist is providing services under a written collaborative practice agreement pursuant to subsection (4) must submit an access-to-care plan (ACP) to the board and department annually.

(a) An ACP shall assist patients in gaining access to appropriate care settings when they present to the pharmacy for

HIV screening and indicate that they lack regular access to primary care. An ACP must include:

1. Procedures to educate such patients about care that would be best provided in a primary care setting and the importance of receiving regular primary care.

2. The pharmacy's plan for collaborative partnership with one or more nearby federally qualified health centers, county health departments, or other primary care settings. The goals of such partnership must include, but need not be limited to, protocols for identifying and appropriately referring patients who have presented to the pharmacy for HIV screening or access to HIV infection prevention drugs and indicates that he or she lacks regular access to primary care.

(8) The board shall adopt rules to implement this section.

Section 2. This act shall take effect July 1, 2024.

T I T L E A M E N D M E N T

Remove lines 4-18 and insert:

authorizing licensed pharmacists to screen for HIV exposure and order and dispense HIV infection prevention drugs under a collaborative practice agreement; requiring pharmacists to be certified by the Board of Pharmacy before ordering and dispensing HIV infection prevention drugs; requiring the board, in consultation with the Board of Medicine and the Board of

Osteopathic Medicine, to adopt rules for such certification; specifying minimum requirements for the certification;

HB 255

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 255 Psychiatric Treatments
SPONSOR(S): Amesty and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 252

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Curry	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Electroconvulsive therapy is a medical procedure most commonly used for patients who suffer with major depression or bi-polar, severe persistent suicidal ideation, mania, or schizophrenia, and who have not responded to other treatments or medications. Psychosurgery is a type of surgical procedure of the brain used to treat certain mental health disorders.

The bill prohibits electroconvulsive treatments and psychosurgical procedures from being performed on a person younger than 18 years of age and requires the patient to give informed written consent before receiving an electroconvulsive treatment or a psychosurgical procedure.

The bill requires electroconvulsive treatments and psychosurgical procedures to only be performed by a physician, and requires a second physician, not directly involved with the patient, to agree that a proposed electroconvulsive treatment or psychosurgical procedure is appropriate prior to the treatment or procedure being performed.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Mental Health and Mental Illness

Mental health is a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to contribute to his or her community.[1] The primary indicators used to evaluate an individual's mental health are:[2]

- **Emotional well-being**- Perceived life satisfaction, happiness, cheerfulness, peacefulness;
- **Psychological well-being**- Self-acceptance, personal growth including openness to new experiences, optimism, hopefulness, purpose in life, control of one's environment, spirituality, self-direction, and positive relationships; and
- **Social well-being**- Social acceptance, beliefs in the potential of people and society as a whole, personal self-worth and usefulness to society, sense of community.

Mental illness is collectively all diagnosable mental disorders or mental health conditions that are characterized by alterations in thinking, mood, or behavior (or some combination thereof) associated with distress or impaired functioning.[3] Thus, mental health refers to an individual's mental state of well-being whereas mental illness signifies an alteration of that well-being. Mental illness affects millions of people in the United States each year. Nearly one in five adults lives with a mental illness.[4] During their childhood and adolescence, almost half of children will experience a mental disorder, though the proportion experiencing severe impairment during childhood and adolescence is much lower, at about 22%.[5]

Mental Health Treatments

There are more than 200 types of mental health disorders.[6] Some of the most common types include:[7]

- Anxiety disorders, including panic disorder, obsessive-compulsive disorder, and phobias;
- Depression, bipolar disorder, and other mood disorders;
- Eating disorders;
- Personality disorders;
- Post-traumatic stress disorder; and
- Psychotic disorders,[8] including schizophrenia.

[1] World Health Organization, *Mental Health: Strengthening Our Response,* https://www.who.int/news-room/fact-sheets/detail/mental-health-strengthening-our-response (last visited January 21, 2024).
[2] Centers for Disease Control and Prevention, *Mental Health Basics*, http://medbox.iiab.me/modules/en-cdc/www.cdc.gov/mentalhealth/basics.htm (last visited January 21, 2024).
[3] *Id*.
[4] National Institute of Mental Health (NIH), *Mental Illness*, https://www.nimh.nih.gov/health/statistics/mental-illness (last visited January 21, 2024).
[5] *Id*.
[6] Cleveland Clinic, *Mental Health Disorders*, available at https://my.clevelandclinic.org/health/diseases/22295-mental-health-disorders, (last visited January 29, 2024).
[7] National Library of Medicine, *Mental Disorders,* available at https://medlineplus.gov/mentaldisorders.html, (last visited January 29, 2024).
[8] Psychotic disorders, also called psychoses, are severe mental disorders that cause abnormal thinking and perceptions. People with psychoses lose touch with reality. Two of the main symptoms are delusions and hallucinations. See National Library of Medicine, *Psychotic Disorders*, available at https://medlineplus.gov/psychoticdisorders.html, (last visited January 29, 2024).

Treatment for mental illness depends on the type of mental disorder the individuals has and the severity. Treatment may include, medication, psychotherapy, hospital and residential treatment programs, brain stimulation treatments and neurosurgical treatments for mental disorders.[9]

- **Medication** is popular treatment method for mental disorders. While they do not cure mental illness, they often help to significantly improve symptoms. Medications may also make other treatment plans, such as such as psychotherapy, more effective.[10] Common psychiatric medications include antidepressants, anti-anxiety medications, mood-stabilizers, and antipsychotics.[11]

- **Psychotherapy**, also referred to as talk therapy, is the most common treatment of mental disorders.[12] Psychotherapy involves the individual talking about his or her condition with a mental health professional. During psychotherapy the person learns about their condition, moods, feelings, thoughts, and behavior and acquire coping and stress management skills.[13] Psychotherapy is typically done one-on-one, but can be done in group settings.[14]

- **Hospital and residential treatment programs** are generally recommended when the mental illness becomes severe and the person is unable to properly care for him- or herself or when the individual is in immediate danger of harming him- or herself. Hospital and residential treatment options include 24-hour inpatient care, intensive outpatient treatment, partial or day hospitalization, or residential treatment, which offers a temporary supportive housing.[15]

- **Brain stimulation treatments** are generally reserved for situations in which medications and psychotherapy have not worked. This treatment is used to treat severe symptoms of mental disorders, including depression. Brain stimulation treatments include electroconvulsive therapy, repetitive transcranial magnetic stimulation,[16] deep brain stimulation[17] and vagus nerve stimulation.[18]

- **Neurosurgical treatment for mental disorders**, also known as psychosurgery, is a surgical procedure performed on the brain by a neurosurgeon. This procedure is used to treat patients with severe and incapacitating mental disorders who have not responded to other treatments.

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[9] Mayo Clinic, *Mental Illness: Diagnosis*, available at https://www.mayoclinic.org/diseases-conditions/mental-illness/diagnosis-treatment/drc-20374974, and Victoria Department of Health, *Neurosurgery for Mental Illness*, available at https://www.health.vic.gov.au/mental-health-and-wellbeing-act-handbook/neurosurgery-for-mental-illness (last visited January 29, 2024).
[10] Mayo Clinic, *Mental Illness: Diagnosis*, available at https://www.mayoclinic.org/diseases-conditions/mental-illness/diagnosis-treatment/drc-20374974, and FamilyDoctor.Org, *Different Types of Mental Health Treatment*, at https://familydoctor.org/different-types-mental-health-treatment/, (last visited January 29, 2024).
[11] Mayo Clinic, *Mental Illness: Diagnosis*, available at https://www.mayoclinic.org/diseases-conditions/mental-illness/diagnosis-treatment/drc-20374974, (last visited January 29, 2024).
[12] Family Doctor.Org, *Different Types of Mental Health Treatment*, at https://familydoctor.org/different-types-mental-health-treatment/, (last visited January 29, 2024).
[13] Supra, note 11.
[14] Supra, note 12.
[15] Supra, note 11.
[16] Transcranial magnetic stimulation is a noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain to improve symptoms of major depression. See. Mayo Clinic, *Transcranial Magnetic Stimulation*, available at https://www.mayoclinic.org/tests-procedures/transcranial-magnetic-stimulation/about/pac-20384625, (last visited January 29, 2024).
[17] Deep brain stimulation is a procedure that involves implanting electrodes within areas of the brain. The electrodes produce electrical impulses that affect brain activity to treat certain medical conditions. Deep brain stimulation is commonly used to treat conditions such as Parkinson's, epilepsy, tourette syndrome, and obsessive-compulsive disorder. See Mayo Clinic, *Deep Brain Stimulation*, available at https://www.mayoclinic.org/tests-procedures/deep-brain-stimulation/about/pac-20384562, (last visited January 29, 2024).
[18] Vagus nerve stimulation is a procedure that involves using a device to stimulate the vagus nerve to send electrical impulses to the brainstem. The impulses change brain functions and alter brain activity to treat various medical conditions, such as treatment-resistant depression, epilepsy, or to help with rehabilitation when recovering from a stroke. Also see Mayo Clinic, *Vagus Nerve Stimulation*, available at https://www.mayoclinic.org/tests-procedures/vagus-nerve-stimulation/about/pac-20384565, National Alliance on Mental Illness, *ECT, TMS and Other Brain Stimulation Therapies,* available at https://www.nami.org/About-Mental-Illness/Treatments/ECT-TMS-and-Other-Brain-Stimulation-Therapies, and Supra, note 9. (last visited January 29, 2024).

Neurosurgery is mostly used to treat severe depression, obsessive-compulsive disorder, and anxiety disorders.[19] In some cases neurosurgery may also be used to treat schizophrenia.[20]

Electroconvulsive Therapy

Electroconvulsive therapy (ECT) is a medical procedure most commonly used for patients who suffer with major depression or bi-polar, serve persistent suicidal ideation, mania, or schizophrenia and who have not responded to other treatments or medications.[21] During the procedure, electrodes are placed on the patients head and a small electric current is passed through the electrodes into the brain to intentionally trigger a brief seizure.[22] This dramatically increases the patient's brain activity which creates changes in the brain chemistry that can quickly improve certain mental health conditions.[23] ECT is performed under general anesthesia and is typically administered by a medically trained team of anesthesiologists, psychiatrists, nurses, or physician assistants.[24]

ECT treatments generally involve a series of six to 12 treatments given two or three times a week for three or four weeks. The number of treatments depends of the severity of the patient's symptoms and how quickly the patient responds to treatment.[25] Prior to having an ECT treatment, a patient may be required to undergo a full evaluation, which may include, medical history, a complete physical exam, psychiatric evaluation, basic blood test, and an electrocardiogram (ECG) to check heart health.[26]

Risks of ECT Treatment

While most consider ECT to be generally safe, there are several risks and side effects associated with the procedure. The risks and side effects may include:[27]

- **Confusion.** A patient may immediately experience confusion after treatment, which generally last from a few minutes to several hours. However, in rare cases confusion may last several days or longer. Confusion is typically more noticeable in older adults.

- **Memory loss.** A patient may experience temporary memory loss or have temporary difficulty learning. Some patients may have difficultly remembering events that occurred in the days, weeks, or even months prior to treatment. Memory problems usually improve within a couple of months after treatment. However, some patients may experience memory loss for longer periods, including permanent gaps in memory.[28]

- **Physical side effects.** The most common physical side effects that patients experience include nausea, headache, fatigue, jaw pain and muscle aches. These side effects can generally be treated with medication and resolve quickly.

[19] Victoria Department of Health, *Neurosurgery for Mental Illness*, available at https://www.health.vic.gov.au/mental-health-and-wellbeing-act-handbook/neurosurgery-for-mental-illness and Very Well Mind, *What is Psychosurgery?*, available at https://www.verywellmind.com/what-is-psychosurgery-5114483, (last visited January 30, 2024).
[20] Hellovaia.com, *Psychosurgery*, available at https://www.hellovaia.com/explanations/psychology/psychological-treatment/psychosurgery/, (last visited January 30, 2024).
[21] Central Florida Behavioral Hospital, *Electroconvulsive Therapy (ECT)*, available at https://centralfloridabehavioral.com/programs-services/electroconvulsive-therapy/, and American Psychiatric Association, *What is Electroconvulsive Therapy ECT*, available at https://www.psychiatry.org/patients-families/ect, (last visited January 29, 2024).
[22] WebMd, *ECT and Other Procedures for Schizophrenia*, available at https://www.webmd.com/schizophrenia/electroconvulsive-therapy, and Mayo Clinic, *Electroconvulsive Therapy*, available at https://www.mayoclinic.org/tests-procedures/electroconvulsive-therapy/about/pac-20393894, (last visited January 29, 2024).
[23] Mayo Clinic, *Electroconvulsive Therapy*, available at https://www.mayoclinic.org/tests-procedures/electroconvulsive-therapy/about/pac-20393894, (last visited January 29, 2024).
[24] American Psychiatric Association, *What is Electroconvulsive Therapy ECT*, available at https://www.psychiatry.org/patients-families/ect, (last visited January 29, 2024).
[25] Supra, note 21.
[26] *Id.*
[27] *Id.*
[28] Supra, note 22.

- **Medical complications.** Medical complications may include complications related to the general risks of anesthesia. Other medical complications include the risk of heart problems. During ECT, the patient's heart rate and blood pressure are elevated, which could lead to serious heart problems.

Psychosurgery

Psychosurgery is a brain surgery performed to treat certain psychiatric disorders involving the selective surgical removal or destruction of nerve pathways for purposes of influencing behavior.[29] The basic concept behind psychosurgery is that if certain parts of the brain are responsible for certain symptoms, then destroying the brain tissue connecting those parts of the brain will essentially help to eliminate those symptoms.[30]

The most well-known example of psychosurgery is the lobotomy.[31] This procedure involved drilling two small holes in a patient's skull and cutting the nerve fibers that connected the front of the brain, which controls personality, decision-making and reasoning, with the other regions of the brain.[32] This procedure often produced serious and irreversible side effects, with many patients left severely brain damaged or dead. Lobotomies were very popular during the 1930s and 1940s. However, upon the introduction of antipsychotic drugs in the 1950s, the use of psychosurgery vastly declined until eventually ending in the mid-1970s.[33] During the late 1990s, psychosurgery began reemerging as a treatment option for psychiatric or mental disorders. However, the procedure still remains banned in some countries.[34]

Modern Psychosurgery

While psychosurgery procedures such as lobotomies are no longer used, modern psychosurgical procedures are used to treat extreme cases of mental disorders when medications and behavioral therapy have failed. However, the surgical techniques used now to perform psychosurgeries are vastly different. The procedures are also much safer and more effective.[35] Modern psychosurgery procedures have fewer detrimental side effects and the risk of permanent damage to the brain is substantially lower.[36] Modern psychosurgery involves destroying tiny bits of brain tissue using heat.[37] The specific areas of the brain that are targeted during the procedure do not effect the patient's intellectual functioning or quality of life.[38]The primary object of the procedure is to control, change, or affect behavioral or emotional disturbances of the patient.[39]

Psychosurgical Procedures

[29] Very Well Mind, What is Psychosurgery?, available at https://www.verywellmind.com/what-is-psychosurgery-5114483, (last visited January 30, 2024).
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.* Also see Springer Link, *Concerns About Concerns About Psychiatric Neurosurgery and How They Can Be Overcome: Recommendations for Responsible Research*, (February 2022), available at https://link.springer.com/content/pdf/10.1007/s12152-022-09485-z.pdf, (last visited January 30, 2024).
[34] Springer Link, *Concerns About Concerns About Psychiatric Neurosurgery and How They Can Be Overcome: Recommendations for Responsible Research*, (February 2022), available at https://link.springer.com/content/pdf/10.1007/s12152-022-09485-z.pdf, (last visited January 30, 2024).
[35] *Id.*
[36] Support the Workers, Psychosurgery: Prefrontal Lobotomy, Cingulotomy, Capsulotomy. Brief History and Modern Use, *available at https://supporttheworkers.org/psychosurgery/, (last visited January 30, 2024).*
[37] Supra, note 28.
[38] *Id.*
[39] Supra, note 33.

The most common psychosurgical procedures used today are anterior cingulotomy, subcaudate tractotomy, limbic leucotomy, and anterior capsulotomy. However, only anterior cingulotomy, anterior capsulotomy, and limbic leucotomy are practiced most often.[40]

- **Anterior cingulotomy** is neurosurgical procedure performed on the anterior cingulate. The anterior cingulate is the part of the brain that is involved in alerting a person to a task's urgency and giving the feeling of satisfaction when the task is complete. Anterior cingulotomy is primarily used to treat patients with treatment-resistant obsessive-compulsive disorder and sometimes major depressive disorder. The procedure has been used since the 1960s. An anterior cingulotomy is performed by a neurosurgeon drilling a small hole into the patient's skull then using a blade to cut a path to access the anterior cingulate cortex. A heated probe is then used to burn away approximately half a teaspoon of the brain tissue in the anterior cingulate cortex. Side effects of the procedure include risk of infection and seizures.[41]

- **Anterior capsulotomy** is used to reduce symptoms of treatment-resistant obsessive-compulsive disorder. The procedure is similar to anterior cingulotomy procedure. However, instead of targeting the cingulate cortex, tiny bits of brain tissue in the region of the brain near the thalamus[42] (called the anterior capsule), are burned away. Anterior capsulotomy is a slightly riskier procedure than anterior cingulotomy and may cause immediate side effects including cerebral edema, delirium, headache, seizures, urinary incontinence, and long-term weight gain.[43]

- **Subcaudate tractotomy** is a procedure that targets the white matter in the brain. The white matter of the brain is made up of a large network of nerve fibers in the brain that allow for the exchange of information and communication between different areas of the brain. It is call white matter because the nerve fibers are covered with a protective sheath called myelin, that gives it a white color.[44] Subcaudate tractotomy is used to treat patients with treatment-resistant depression, anxiety, and obsessive-compulsive disorder.[45] The procedure is considered just as effective as anterior cingulotomy, but appears to cause more side effects.[46]

- **Limbic leucotomy** is a combination of two procedures, the anterior cingulotomy and subcaudate tractotomy. This procedure is usually performed if a patient does not respond to anterior cingulotomy. The side effects are typically short term and include, transient hallucinations, amnesia, and mania.[47]

The recovery process after psychosurgery varies depending on the patient and procedure. Typically, a patient remains in the hospital after surgery, followed by a short recovery at home. The hospital stay can range from several days to two to three weeks. Most patients are able to see the results nine months to a year after surgery.[48]

Electroconvulsive and Psychosurgical Procedures in Florida

Current law requires written patient consent for electroconvulsive therapy or psychosurgery. If the patient is a minor or incompetent, consent must be given by the patient's guardian. Written consent must be obtained after disclosure to the patient or to the patient's guardian, if applicable, the purpose of

[40] Supra, note 28.
[41] *Id.*
[42] The thalamus is an egg-shaped structure in the middle of the brain. It is the relay station of all incoming motor movement of the brain and sensory information, hearing, taste, sight, and touch, but not smell, from the body to the brain. Information passes through the thalamus before being routed to the brain's cerebral cortex, the outermost layer of the brain. See Cleveland Clinic, *Thalamus,* available at https://my.clevelandclinic.org/health/body/22652-thalamus, (last visited January 30, 2024).
[43] Supra, note 28.
[44] Cleveland Clinic, *White Matter Disease,* available at https://my.clevelandclinic.org/health/diseases/23018-white-matter-disease, (last visited January 30, 2024).
[45] Supra, note 28.
[46] *Id.*
[47] *Id.*
[48] Supra, note 28.

the procedure, common side effects after the procedure, the approximate number of procedures considered necessary for treatment, and the patient or the patient's guardian's right to revoke any consent given prior to or between treatments.[49] Current law does not specify the method (oral or written) in which disclosure to the patient must be given.

Before electroconvulsive therapy or a psychosurgery procedure may be performed, a second physician, who is not directly involved with the patient, must review the patient's treatment record and agree to the proposed treatment in writing. The agreement must be signed by both physicians and documented in the patient's treatment record.[50]

Current law does not define electroconvulsive or psychosurgical procedures.

Effect of the Bill

The bill prohibits electroconvulsive treatment and psychosurgical procedures from being performed on a person younger than 18 years of age and requires electroconvulsive treatment or psychosurgical procedures to only be performed by a physician.

The bill requires informed written consent. The informed written consent must include written disclosure and must be obtained from the patient by the physician prior to electroconvulsive treatment or a psychosurgical procedure.

The bill also requires a second physician, not directly involved with the patient, to agree that the proposed electroconvulsive treatment or psychosurgical procedure is appropriate prior to the patient's physician performing the proposed treatment or procedure. Current law only requires the physicians to agree to the proposed procedure. The bill makes it clear that the physicians must agree on the appropriateness of the treatment or procedure to be performed on the patient.

The bill defines electroconvulsive treatment to mean psychiatric treatment that involves sending an electric current through the brain while the patient is under anesthesia and defines a psychosurgical procedure as a neurological surgery used to treat a mental disorder.

The bill provides an effect date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 458.325, F.S., relating to electroconvulsive and psychosurgical procedures.
Section 2: Providing an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[49] S. 458.325(1), F.S.
[50] S. 458.325(2), F.S.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The department has sufficient rulemaking authority in current law to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to psychiatric treatments; amending s. 458.325, F.S.; defining the terms "electroconvulsive treatment" and "psychosurgical procedure"; providing that only a physician may perform electroconvulsive treatment and psychosurgical procedures; prohibiting the performance of electroconvulsive treatment and psychosurgical procedures on minors; making technical changes; providing an effective date.

WHEREAS, electroconvulsive therapy (ECT) is an experimental technique the efficacy of which has not definitively been proven and which has dangerous and potentially permanent harmful or life-threatening side effects, including brain damage and memory loss, the extent of which is still unknown, and

WHEREAS, literature regarding the administration of ECT on children and adolescents consists mainly of single case study reports and uncontrolled studies and does not offer controlled studies, reliably applied criteria, or valid assessment scales, and

WHEREAS, psychosurgery is an experimental technique the efficacy of which has not been proven and which has dangerous and potentially permanent harmful or life-threatening side effects, and

WHEREAS, the use of invasive and possibly damaging

treatment without scientific basis in the context of the still-developing neurological systems of children and adolescents cannot be justified, and

WHEREAS, on January 20, 2000, the National Council on Disability (NCD), an independent federal agency, first made recommendations to the President and Congress which included the following: "Mental health treatment should be about healing, not punishment. Accordingly, the use of aversive treatments, including physical and chemical restraints, seclusion, and similar techniques that restrict freedom of movement, should be banned. Also, public policy should move toward the elimination of electroconvulsive therapy and psychosurgery as unproven and inherently inhumane procedures. Effective humane alternatives to these techniques exist now and should be promoted," and continues to stand by this recommendation 23 years later, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 458.325, Florida Statutes, is amended to read:

458.325 Electroconvulsive <u>treatment</u> and psychosurgical procedures.—

<u>(1) As used in this section, the term:</u>

<u>(a) "Electroconvulsive treatment" means psychiatric</u>

treatment that involves sending an electric current through the brain while the patient is under anesthesia.

(b) "Psychosurgical procedure" means neurological surgery used to treat a mental disorder.

(2) Only a physician may perform electroconvulsive treatment and psychosurgical procedures.

(3) Electroconvulsive treatment and psychosurgical procedures may not be performed on a person younger than 18 years of age.

(4) Before performing ~~In each case of utilization of~~ electroconvulsive treatment or a psychosurgical procedure ~~procedures~~, a physician must first obtain informed ~~prior~~ written consent from ~~shall be obtained after disclosure to~~ the patient, if he or she is competent, or from ~~to~~ the patient's guardian, if the patient ~~he or she~~ is ~~a minor or~~ incompetent. The informed written consent must include disclosure~~,~~ of the purpose of the procedure, the common side effects thereof, alternative treatment modalities, and the approximate number of such procedures considered necessary and that any consent given may be revoked by the patient or the patient's guardian before ~~prior to~~ or between treatments.

(5)~~(2)~~ Before a physician may perform electroconvulsive treatment or a psychosurgical procedure ~~convulsive therapy or psychosurgery may be administered~~, another physician not directly involved with the patient must review the patient's

treatment record ~~shall be reviewed~~ and agree that the proposed electroconvulsive treatment or psychosurgical procedure is appropriate for ~~convulsive therapy or psychosurgery agreed to by one other physician not directly involved with~~ the patient. Such agreement must ~~shall~~ be documented in the patient's treatment record and ~~shall~~ be signed by both physicians.

Section 2. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	_____	

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Amesty offered the following:

Amendment (with title amendment)

Remove line 57 and insert:

(3) Electroconvulsive treatment and psychosurgical procedures may not be performed on a person younger than 16 years of age unless:

(a) The physician certifies in writing, that in reasonable medical judgement, there is a medical necessity for electroconvulsive treatment or a psychosurgical procedure.

(b) Two psychiatrists, as defined under s. 394.455, who do not work within the same medical practice, agree in writing, in reasonable medical judgement, that the proposed electroconvulsive treatment or psychosurgical procedure is

appropriate for the patient. Such agreement must be signed by both psychiatrists and documented in the patient's treatment record.

T I T L E A M E N D M E N T

Remove line 8 and insert:
psychosurgical procedures on persons 16 years or younger; providing an exception; making technical

HB 493

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 493 Pharmacy
SPONSOR(S): Roach
TIED BILLS: **IDEN./SIM. BILLS:** SB 444

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		DesRochers	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Florida Pharmacy Act (Act) regulates the practice of pharmacy in Florida. The Board of Pharmacy (Board) adopts rules to implement the provisions of the Act and sets standards of practice within the state. Any person who operates a pharmacy in Florida must have a permit in one of the seven categories: community pharmacy, institutional pharmacy, nuclear pharmacy, special pharmacy, internet pharmacy, nonresident sterile compounding pharmacy, or special sterile compounding pharmacy. A pharmacist must be present and on duty for the prescription department of a pharmacy to be considered open; however the prescription department is not considered closed if the pharmacist briefly leaves to tend to personal needs or counsel patients.

HB 493 creates a new pharmacy permit category for the operation of a remote site pharmacy. A remote site pharmacy is a location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an off-site prescription department manager. In addition to meeting all the requirements in rule and statute for permitting pharmacies, a remote pharmacy must be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy; maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days; display a sign, visible by the public, which indicates that the facility is a remote site pharmacy and that it is under 24-hour video surveillance; maintain a policies and procedures manual which must be made available to the Board of Pharmacy or its agent upon request; and designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility.

The bill authorizes a remote-site pharmacy to store, hold, and dispense all medicinal drugs, including proprietary drugs and controlled substances. However, a remote-site pharmacy may not dispense Schedule II controlled substances listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

The prescription department manager must visit the remote-site pharmacy as often as the Board's schedule states. During remote site pharmacy visits, the prescription department manager must inspect the pharmacy, address personnel matters, and provide clinical services for patients.

The bill authorizes a pharmacist to serve as the prescription department manager for up to three remote site pharmacies that are under common control of the same supervising pharmacy. The maximum allowable pharmacist-pharmacy technician ratio is 1:6.

The bill authorizes a registered pharmacy technician working in a remote site pharmacy under the remote supervision of a pharmacist to fill, compound, and dispense medicinal drugs.

The bill has a significant, negative fiscal impact on DOH and no impact on local governments. See Fiscal Analysis.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Pharmacy Regulation

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.[1] The Board of Pharmacy (Board) is tasked with adopting rules to implement the provisions of the act and setting standards of practice within the state.[2] Any person who operates a pharmacy in Florida must have a permit, and as of June 30, 2023, there were 10,901 permitted pharmacies in the state.[3] The following permits are issued by the Department of Health (DOH):

- Community pharmacy – A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[4]
- Institutional pharmacy – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[5]
- Nuclear pharmacy – A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals.[6]
- Special pharmacy – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[7]
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[8]
- Nonresident sterile compounding pharmacy – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.[9]
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.[10]

A pharmacy must pass an on-site inspection for a permit to be issued,[11] and the permit is valid only for the name and address to which it is issued.[12]

[1] Chapter 465, F.S.
[2] Sections 465.005, 465.0155, and 465.022, F.S.
[3] Department of Health, *2024 Agency Legislative Bill Analysis for House Bill 493*, (Nov. 20, 2023), on file with the Healthcare Regulation Subcommittee.
[4] Sections 465.003(20)(a)1. and 465.018, F.S.
[5] Sections 465.003(20)(a)2. and 465.019, F.S.
[6] Sections 465.003(20)(a)3. and 465.0193, F.S.
[7] Sections 465.003(20)(a)4. and 465.0196, F.S.
[8] Sections 465.003(20)(a)5. and 465.0197, F.S.
[9] Section 465.0158, F.S.
[10] Rules 64B16-28.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and need to hold a special sterile compounding permit if it engages in sterile compounding.
[11] *Id*.
[12] Rule 64B16-28.100, F.A.C.

Regulation of Pharmacists and Pharmacy Technicians

Pharmacists

Licensure Requirements

A pharmacist is a person who is licensed under the act to practice the profession of pharmacy.[13] To be licensed as a pharmacist in Florida, a person must:[14]

- Be at least 18 years of age;
- Complete an application and remit an examination fee;
- Hold a degree from an accredited and approved school or college of pharmacy;[15]
- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

During each biennial licensure renewal cycle, a pharmacist must complete at least 30 hours of Board-approved continuing education.[16] If a pharmacist is certified to administer vaccines or epinephrine, the pharmacist must complete a 3-hour continuing education course on the safe and effective administration of vaccines and epinephrine autoinjections as a part of the biennial licensure renewal.[17]

Scope of Practice

The practice of the profession of pharmacy includes:[18]

- Compounding,[19] dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[20]
- Administering epinephrine injections;[21] and
- Administering antipsychotic medications by injection.[22]

Pharmacists are specifically prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.[23]

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[13] Section 465.003(19), F.S.
[14] Section 465.007, F.S. DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.
[15] If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the Board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist.
[16] Section 465.009, F.S.
[17] Section 465.009(6), F.S.
[18] Section 465.003(22), F.S.
[19] Rule 64B16-27.700, F.A.C., defines compounding a professional act by a pharmacist incorporating ingredients to create a finished product for dispensing to a patient or to a practitioner for administration to a patient. The American Pharmacists Association, citing the U.S. Pharmacopeia Convention (USP) defines compounding as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/ pharmacist/compounder relationship in the course of professional practice." *See* https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs (last visited Jan. 21, 2024).
[20] *See* s. 465.189, F.S.
[21] *Id*.
[22] Section 465.1893, F.S.
[23] *Supra* note 18.

Only a pharmacist or registered intern may:[24]

- Supervise or be responsible for the controlled substance inventory;
- Receive verbal prescriptions from a prescriber;
- Interpret and identify prescription contents;
- Engage in consultation with a health care practitioner regarding the interpretation of a prescription and date in a patient's profile record;
- Engage in professional communication with health care practitioners;
- Advise or consult with a patient, both as to the prescription and the patient profile record; and
- Perform certain duties related to the preparation of parenteral and bulk solutions.

Pharmacists must perform the final check of a completed prescription, thereby assuming complete responsibility for its preparation and accuracy.[25] A pharmacist must be personally available at the time of dispensing.[26] A prescription department is considered closed if a Florida-licensed pharmacist is not present and on duty unless the pharmacist leaves the prescription department to:[27]

- Consult, respond to inquiries, or provide assistance to customers or patients;
- Attend to personal hygiene needs; or
- Perform functions for which the pharmacist is responsible provided that such activities are performed in a manner that is consistent with the pharmacist's responsibility to provide pharmacy services.

Prescription Department Managers

Each community pharmacy must have designate a licensed pharmacist as a prescription department manager.[28] The prescription drug manager is responsible for maintaining all drug records, providing for the security of the prescription department, and ensuring that the all regulations of the practice of the profession of pharmacy are followed.[29] A pharmacist may only serve as the prescription department manager of one pharmacy.[30] However, the Board may grant an exception based on circumstances, such as the proximity of the pharmacies and the workload of the pharmacist.

Pharmacy Technicians

Registration Requirements

Pharmacy technicians assist pharmacists in dispensing medications and are accountable to a supervising pharmacist who is legally responsible for the care and safety of the patients served.[31] A person must register with DOH to practice as a pharmacy technician. To register, an individual must:[32]

- Be at least 17 years of age;
- Submit an application and remit an application fee; and
- Complete a Board-approved pharmacy technician training program.[33]

[24] Rule 64B16-27.1001(1)-(2), F.A.C. Section 465.003(12), F.S., defines a pharmacy intern as a person who is currently registered in, and attending, or is a graduate of a duly accredited college or school of pharmacy and is properly registered with DOH. The American Pharmacist Association, citing the U.S.
[25] Rule 64B16-27.1001(3), F.A.C.
[26] Rule 64B16-27.1001(4), F.A.C.
[27] Section 465.003(20)(b), F.S.
[28] Rules 64B16-27.104 and 64B16-27.450, F.A.C.
[29] *Id*.
[30] *Id*.
[31] Pharmacy Technician Certification Board, *Pharmacy Technicians*, available at https://www.ptcb.org/who-we-serve/pharmacy-technicians#.Wj1PsGyouUk (last visited on Jan. 21, 2024).
[32] Section 465.014(2), F.S.
[33] An individual is exempt from the training program if he or she was registered as a pharmacy technician before January 1, 2011, and either worked as a pharmacy technician at least 1,500 hours under a licensed pharmacists or received certification from an accredited pharmacy technician program.

The pharmacy technician must renew the registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours, 4 of which must be live.[34]

Pharmacy Technician Training Programs

A pharmacy technician may only be registered with DOH if he or she completes a Board-approved training program. These include pre-approved training programs that were accredited on or before December 1, 2018, by certain accreditation entities, such as the Accreditation Council on Pharmacy Education, as well as pharmacy technician training programs provided by a branch of the United States Armed Forces whose curriculum was developed on or before June 1, 2018.[35]

The Board may review and approve other training programs that do not meet the criteria for pre-approval. Such programs must be licensed by the Commission for Independent Education or equivalent licensing authority or be within the public school system of this state, and offer a course of study that includes:[36]

- Introduction to pharmacy and health care systems;
- Confidentiality;
- Patient rights and the Health Insurance Portability and Accountability Act (HIPAA);
- Relevant federal and state law;
- Pharmaceutical topics, including medical terminology, abbreviations, and symbols; medication safety and error prevention; and prescriptions and medication orders;
- Records management and inventory control, including pharmaceutical supplies, medication labeling, medication packaging and storage, controlled substances, and adjudication and billing;
- Interpersonal relations and ethics, including diversity of communications, empathetic communications, ethics governing pharmacy practice, patient and caregiver communications; and
- Pharmaceutical calculations.

The training program must provide the Board with educational and professional background of its faculty.[37] A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.[38]

The Board may also review and approve employer-based pharmacy technician training programs. An employer-based program must be offered by a Florida-permitted pharmacy, or affiliated group of pharmacies under common ownership.[39] The program must consist of 160 hours of training over a period of no more than 6 months and may only be provided to the employees of that pharmacy.[40] The employer-based training program must:[41]

- Meet the same qualifications as required for non-employment based pharmacy technician training programs as indicated above;
- Provide an opportunity for students to evaluate learning experiences, instructional methods, facilitates, and resources;
- Ensure that self-directed learning experience, such as home study or web-based courses, evaluate the participant's knowledge at the completion of the learning experience; and
- Designate a person to assume responsibility for the registered pharmacy technician training program.

Scope of Practice

[34] Section 465.014(6), F.S.
[35] Rule 64B16-26.351(1)-(2), F.A.C.
[36] Rule 64B16-26.351(3)(b), F.A.C.
[37] Rule 64B16-26.351(3)(e), F.A.C.
[38] *Id*.
[39] Rule 64B16-26.351(4), F.A.C.
[40] *Id*.
[41] *Id*.

A registered pharmacy technician may not engage in the practice of the profession of pharmacy; however, a licensed pharmacist may delegate those duties, tasks, and functions that do not fall within the definition of the practice of professional pharmacy.[42] Registered pharmacy technicians' responsibilities include: [43]

- Retrieval of prescription files;
- Data entry;
- Label preparation;
- Counting, weighing, measuring, and pouring of prescription medication;
- Initiation of communication with a prescribing practitioner regarding requests for prescription refill authorization, obtaining clarification on missing or illegible information on prescriptions, and confirmation of information such as names, medication, strength, directions, and refills;
- Acceptance of authorization for prescription renewals; and
- Any other mechanical, technical, or administrative tasks which do not themselves constitute the practice of the profession of pharmacy.

A licensed pharmacist must directly supervise the performance of a registered pharmacy technician,[44] and is responsible for acts performed by persons under his or her supervision.[45] A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.[46] If technological means are used by a pharmacist to supervise the pharmacy technician(s), the technological means must be sufficient for the pharmacist to provide the personal assistance, direction, and approval required to meet the standard of practice for the delegated tasks.[47]

The Board specifies, by rule, certain acts that registered pharmacy technicians are prohibited from:[48]

- Receiving new verbal prescriptions or any change in the medication, strength, or directions of an existing prescription;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Monitoring prescription drug usage;
- Transferring a prescription;
- Overriding clinical alerts without first notifying the pharmacist;
- Preparing a copy of a prescription or reading a prescription to any person for the purpose of providing reference concerning treatment of the patient for whom the prescription was written;
- Engaging in patient counseling; or
- Engaging in any other act that requires the exercise of a pharmacist's professional judgment.

A registered pharmacy technician must wear an identification badge with a designation as a "registered pharmacy technician" and identify herself or himself as a registered pharmacy technician in telephone or other forms of communication.[49]

Pharmacist-to-Technician Ratios

[42] Section 465.014(1), F.S.
[43] Rule 64B16-27.420(1), F.A.C.
[44] Direct supervision means supervision by a pharmacist who is on the premises at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who is readily available to provide personal assistance, direction, and approval throughout the time the delegated tasks are being performed (r. 64B16-27.4001(2)(a), F.A.C.)
[45] Rule 64B16-27.1001(7), F.A.C.
[46] Rule 64B16-27.4001(2)(b), F.A.C.
[47] *Id.*
[48] Rule 64B16-27.420(2), F.A.C.
[49] Rule 64B16-27.100(2), F.A.C.

When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient populations.[50]

Current law prohibits a pharmacist from supervising more than one registered pharmacy technician, unless otherwise permitted by Board rules.[51] The guidelines include the following restrictions:[52]

- A pharmacist engaging in sterile compounding may supervise up to 3 registered pharmacy technicians.
- A pharmacist who is not engaged in sterile compounding may supervise up to 4 registered pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to 6 registered pharmacy technicians, as long as the pharmacist or pharmacy is not involved in sterile compounding.
- In a pharmacy that dispenses medicinal drugs in a physically separate area[53] of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to 6 registered pharmacy technicians.

In all other situations, the Board rules provide the prescription department manager or the consultant pharmacist of record with the discretion to use their independent professional judgment to determine and set the appropriate pharmacist-technician supervision ratios.[54]

Telehealth

Telehealth means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide the following, nonexhaustive types of health care services:[55]

- assessment, diagnosis, consultation, treatment, and monitoring of a patient;
- transfer of medical data;
- patient and professional health-related education;
- public health services; and
- health administration.

Telehealth providers mean any Florida-licensed or Florida-certified individual who provides health care and related services using telehealth, including pharmacists. Current law also recognizes telehealth providers who are licensed under a multistate health care licensure compact of which Florida is a member state. Current law lets health care professionals not licensed in Florida to use telehealth as long as they register with the applicable Board (e.g., The Board of Pharmacy) and provides health care services within the applicable scope of practice (e.g., the practice of pharmacy) established by Florida law or rule (e.g., the Florida Pharmacy Act).[56]

Current law specifies that the delivery of health care services occurs at the place of the patient's location (or the patient's county of residence).[57] A telehealth provider must document the health care services provided to a patient via telehealth in the patient's medical record.[58]

Current law holds telehealth providers to the duty to practice in a manner consistent with their scope of practice and the prevailing professional standard of practice for a health care professional who provides in-person health care services to patients in this state. A nonphysician telehealth provider (e.g., a

[50] Rule 64B16-27.410(1), F.A.C.
[51] Section 465.014(1), F.S.
[52] Rule 64B16-27.410, F.A.C.
[53] A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.
[54] Rule 64B16-27.410(7), F.A.C.
[55] s. 456.47(1)(a), F.S.
[56] *Id*., ss. 456.47(4), (6), F.S. Registration is not required in the event an out-of-state licensed health care professional provides telehealth services in response to an emergency medical condition or in consultation with a Florida-licensed health care professional who has ultimate authority over the diagnosis and care of the patient.
[57] s. 456.47(5), F.S.
[58] s. 456.47(3), F.S.

pharmacist) using telehealth and acting within his or her relevant scope of practice is not in violation of the practice of medicine or an attempt to practice medicine without a license to practice in Florida.[59]

Telepharmacy

Telepharmacy is the provision of pharmaceutical care by pharmacies and pharmacists through the use of telepharmacy technologies to patients or their agents at a distance.[60] Telepharmacy operations include, but are not limited to, drug review and monitoring, dispensing of medications, medication therapy management, clinical consultation, and patient counseling.[61]

Effect of Proposed Changes

HB 493 creates a remote-site pharmacy permit. A remote-site pharmacy includes every location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an off-site pharmacist acting in the capacity of prescription department manager.

Remote Site Pharmacy

The bill requires a DOH-issued permit to operate a remote-site pharmacy. A remote-site pharmacy must:

- Be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy;[62]
- Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days;
- Display a sign, visible by the public, which indicates that the facility is a remote site pharmacy and that it is under 24-hour video surveillance;
- Maintain a policies and procedures manual which must be made available to the Board of Pharmacy or its agent upon request. The policies and procedures manual must include at the very least all of the following:
    - A description of how the pharmacy will comply with federal and state laws and rules.
    - The procedures for supervising the remote site pharmacy and counseling its patients.
    - The procedures for reviewing the prescription drug inventory and drug records maintained by the remote site pharmacy.
    - The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.
    - The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote-site pharmacy's operation.
    - The procedures for use of the state prescription drug monitoring program by the prescription department manager before they may authorize the dispensing of any controlled substance.
    - The procedures for maintaining a perpetual inventory of the controlled substances listed in Schedule II of s. 893.03, F.S.
    - The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote site pharmacy.
- Designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility.

[59] s. 456.47(2), F.S.
[60] National Association of Boards of Pharmacy, "Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy," https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/ (last visited Jan. 21, 2024). Telepharmacy technologies means secure electronic communications, information exchange, or other methods that meet state and federal requirements.
[61] E. Alexander et al, *ASHP Statement on Telepharmacy*, 74 AM J HEALTH-SYSTEM PHARM., e236 (May 2017), available at https://academic.oup.com/ajhp/article-abstract/74/9/e236/5102780?redirectedFrom=fulltext (last visited Jan. 21, 2024).
[62] The bill defines a supervising pharmacy as a Florida-licensed pharmacy that employs or contracts with a Florida-licensed pharmacist who remotely supervises a registered pharmacy technician at a remote site pharmacy at a ratio of one pharmacist to up to six registered pharmacy technicians.

DOH must issue a permit if the Board certifies that an application for a permit complies with the laws and rules governing pharmacies.

Operation of a Remote Site Pharmacy

The bill authorizes a remote-site pharmacy to store, hold, and dispense all medicinal drugs, including proprietary drugs and controlled substances. However, a remote site pharmacy may not dispense Schedule II controlled substances[63] listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

The prescription department manager must visit the remote site pharmacy as often as the Board schedule states. During remote-site pharmacy visits, the prescription department manager must inspect the pharmacy, address personnel matters, and provide clinical services for patients.

Generally, a remote-site pharmacy may not be open when the supervising pharmacy is closed. However, the bill creates two exceptions. First, when a pharmacist employed by or under contract with a supervising pharmacy is present at the remote-site pharmacy or is providing remote supervision as required under the bill, the remote site pharmacy may be open. Second, when a pharmacy under contract with the supervising pharmacy is present at the remote-site pharmacy or is providing remote supervision as required under the bill, the remote-site pharmacy may be open.

Generally, a registered pharmacist cannot serve as the prescription department manager in more than one location. However, the bill authorizes a pharmacist to serve as the prescription department manager for up to three remote-site pharmacies that are under common control of the same supervising pharmacy. The maximum allowable pharmacist-pharmacy technician ratio is 1:6.

Pharmacy Technicians

The bill authorizes a registered pharmacy technician working in a remote-site pharmacy under the remote supervision of a pharmacist to fill, compound, and dispense medicinal drugs.

[63] Section 893.03(2), F.S., defines a Schedule II drug as a substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment, and the abuse of the substance may lead to severe psychological or physical dependence.

Board of Pharmacy

The bill grants the Board of Pharmacy rulemaking authority to adopt rules as necessary to specify additional criteria for a remote-site pharmacy. Any additional criteria adopted by the board must be limited to rules concerning one or more of the following:

- Application requirements.
- Structural and equipment requirements.
- Training requirements.
- Inventory recordkeeping and storage requirements.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.003, F.S., relating to definitions.
Section 2: Amends s. 465.014, F.S., relating to pharmacy technician.
Section 3: Amends s. 465.015, F.S., relating to violations and penalties.
Section 4: Creates s. 465.0198, F.S., relating to remote-site pharmacy permits.
Section 5: Amends s. 465.022, F.S., relating to pharmacies; general requirements; fees.
Section 6: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to DOH, the Department will require 7 FTEs to implement the provisions of this bill.[64]

   - 2 FTEs (Government Analyst II) to process new permit applications.
   - 4 FTEs (1 Senior Attorney, 2 Government Analyst II, and 2 Investigation Specialist II) to handle complaints, investigations, and prosecution cases.
   - 1 FTE (System Project Consultant) to establish and maintain additional transactions in the Enforcement Information Database System (LEIDS), the Online Service Portal (Versa Online) the License Verification Search Site, and the Board of Pharmacy website.

   According to DOH, the total estimated annual cost is $982,229 in the following categories:[65]

   Annual Estimated Cost
   - Salary: $759,732/Recurring
   - Salary Rate: 533,325 units of rate
   - Expense: $62,125/Recurring + $46,613/Non-recurring
   - Human Resources: $2,519
   - Contracted Services: $111,240/Non-recurring

   Because the bill does not authorize a fee for this new permit type, it is unclear how DOH will cover the costs of implementing its provisions.

[64] *Supra*, FN 3 at p. 6-7.
[65] *Id*. at 7-8.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
   None.

2. Expenditures:
   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:
None.

D. FISCAL COMMENTS:
None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:
   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:
   None.

B. RULE-MAKING AUTHORITY:
The Board has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy; amending s. 465.003, F.S.; revising the definition of the term "dispense"; revising the definition of the term "pharmacy" to include remote-site pharmacies; revising construction of the term "not present and on duty"; amending s. 465.014, F.S.; authorizing registered pharmacy technicians to dispense medicinal drugs under certain circumstances; providing an exception to certain supervision limitations; amending s. 465.015, F.S.; providing applicability; exempting certain registered pharmacy technicians from specified prohibitions; creating s. 465.0198, F.S.; defining the terms "supervising pharmacy" and "telepharmacy"; providing for the permitting of remote-site pharmacies; requiring a licensed or consultant pharmacist to serve as the prescription department manager of a remote-site pharmacy; requiring remote-site pharmacies to notify the Department of Health of a change in the pharmacy's prescription department manager within a specified timeframe; providing requirements for remote-site pharmacies; authorizing remote-site pharmacies to store, hold, and dispense medicinal drugs; prohibiting the dispensing of Schedule II medications at remote-site pharmacies unless a

pharmacist is present; requiring prescription department managers to visit remote-site pharmacies, based on a certain schedule, to perform specified tasks; prohibiting remote-site pharmacies from being open when the supervising pharmacy is closed unless a certain pharmacist is present or providing remote supervision at the remote-site pharmacy; prohibiting registered pharmacists from serving as prescription department managers for more than three remote-site pharmacies under certain circumstances; authorizing the Board of Pharmacy to adopt specified rules; amending s. 465.022, F.S.; exempting registered pharmacists serving as prescription department managers for remote-site pharmacies from certain practice limitations; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (13) and (20) of section 465.003, Florida Statutes, are amended to read:

465.003 Definitions.—As used in this chapter, the term:

(13) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist, or by a registered pharmacy technician who is remotely supervised by an offsite pharmacist, to the ultimate consumer or her or his

agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

(20)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, ~~and~~ an Internet pharmacy, and a remote-site pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location

where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of the profession of pharmacy.

6. The term "remote-site pharmacy" includes every location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an offsite pharmacist acting in the capacity of a prescription department manager.

(b) The pharmacy department of any permittee is ~~shall be~~ considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" may ~~shall~~ not be construed to prevent any of the following:

1. A pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers.

2. A pharmacist from~~,~~ attending to personal hygiene needs.

3. A pharmacist from~~, or~~ performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

4. An offsite pharmacist, acting in the capacity of a prescription department manager, from remotely supervising a registered pharmacy technician at a remote-site pharmacy.

Section 2. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003, and a registered pharmacy technician operating under remote supervision of an offsite pharmacist under s. 465.0198 may dispense medicinal drugs under such supervision. All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her

supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician, except as provided in s. 465.0198 or unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician.

Section 3. Paragraph (b) of subsection (1) and paragraph (b) of subsection (2) of section 465.015, Florida Statutes, are amended to read:

465.015 Violations and penalties.—

(1) It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy:

(b) In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs. This paragraph does not apply to any person who owns, operates, maintains, opens, establishes, conducts, or has charge of a

remote-site pharmacy under s. 465.0198.

(2) It is unlawful for any person:

(b) To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, ~~or~~ is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist, or is not a registered pharmacy technician at a remote-site pharmacy who is acting under remote supervision of a licensed pharmacist pursuant to s. 465.0198.

Section 4. Section 465.0198, Florida Statutes, is created to read:

465.0198 Remote-site pharmacy permits.—

(1) As used in this section, the term:

(a) "Supervising pharmacy" means a pharmacy licensed in this state which employs or contracts with a pharmacist licensed in this state who remotely supervises a registered pharmacy technician at a remote-site pharmacy at a ratio of one pharmacist to up to six registered pharmacy technicians.

(b) "Telepharmacy" means the practice of pharmacy by a pharmacist located in this state using telecommunications or other automations and technologies to provide or supervise the provision of pharmacy services to patients and their agents who are located at sites other than where the pharmacist is located, including dispensing of prescriptions to and counseling of

patients.

(2) Any person desiring a permit to operate a remote-site pharmacy must apply to the department. If the board certifies that the application complies with the laws and rules of the board, the department must issue the permit. A permit may not be issued unless a licensed pharmacist or consultant pharmacist is designated as the prescription department manager responsible for the oversight of the remote-site pharmacy. The permittee must notify the department within 10 days after any change of the prescription department manager.

(3) A remote-site pharmacy must comply with all of the following:

(a) Be jointly owned by or operated under a contract with a supervising pharmacy.

(b) Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days.

(c) Display a sign visible to the public indicating that the location is a remote-site pharmacy and that the facility is under 24-hour video surveillance.

(d) Maintain a policies and procedures manual, which must be made available to the board or its agent upon request and must include, but need not be limited to, all of the following:

1. A description of how the pharmacy will comply with federal and state laws and rules.

2. The procedures for supervising the remote-site pharmacy and counseling its patients.

3. The procedures for reviewing the prescription drug inventory and drug records maintained by the remote-site pharmacy.

4. The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.

5. The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote-site pharmacy's operation.

6. The procedures for use of the state prescription drug monitoring program by the prescription department manager before he or she may authorize the dispensing of any controlled substance.

7. The procedures for maintaining a perpetual inventory of the controlled substances listed in Schedule II of s. 893.03.

8. The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote-site pharmacy.

(4) A remote-site pharmacy may store, hold, or dispense any medicinal drug, including proprietary drugs and controlled substances. However, a remote-site pharmacy may not dispense Schedule II controlled substances listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

(5) The prescription department manager must visit the remote-site pharmacy, based on a schedule determined by the board, to inspect the pharmacy, address personnel matters, and provide clinical services for patients.

(6) A remote-site pharmacy may not be open when the supervising pharmacy is closed, unless a pharmacist employed by or under contract with the supervising pharmacy, or a pharmacy under contract with the supervising pharmacy, is present at the remote-site pharmacy or is providing remote supervision as required under this section.

(7) A registered pharmacist may not serve as the prescription department manager for more than three remote-site pharmacies that are under common control of the same supervising pharmacy, at a ratio of one pharmacist to up to six registered pharmacy technicians at each remote-site pharmacy.

(8) The board may adopt rules as necessary to specify additional criteria for a remote-site pharmacy. Any additional criteria adopted by the board must be limited to rules concerning one or more of the following:

(a) Application requirements.

(b) Structural and equipment requirements.

(c) Training requirements.

(d) Inventory recordkeeping and storage requirements.

Section 5. Paragraph (c) of subsection (11) of section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.—

(11) A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

(c) A registered pharmacist may not serve as the prescription department manager in more than one location, except as authorized under s. 465.0198, unless approved by the board.

Section 6. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	___ (Y/N)
ADOPTED AS AMENDED	___ (Y/N)
ADOPTED W/O OBJECTION	___ (Y/N)
FAILED TO ADOPT	___ (Y/N)
WITHDRAWN	___ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Roach offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (20) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(20)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, ~~and~~ an Internet pharmacy, and a remote-site pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of the profession of pharmacy.

6. The term "remote-site pharmacy" means a location where medicinal drugs are dispensed by a supervising pharmacist as defined in s. 465.0198 who is acting in the capacity of a

prescription department manager and remotely supervising a registered pharmacy technician handling the sales transactions and delivery of the drugs.

(b) The pharmacy department of any permittee is ~~shall be~~ considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" may ~~shall~~ not be construed to prevent any of the following:

1. A pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers.

2. A pharmacist from~~,~~ attending to personal hygiene needs.

3. A pharmacist from~~, or~~ performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

4. A supervising pharmacist as defined in s. 465.0198, acting in the capacity of a prescription department manager, from remotely supervising a registered pharmacy technician at a remote-site pharmacy.

Section 2. Subsection (1) of section 465.014, Florida Statutes, is amended to read, and Subsection (10) of section 465.014, Florida Statutes, is created to read:

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy as defined in s. 465.003, except that a licensed

pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003. Except as otherwise provided in this section, a~~A~~ll such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician or unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician.

(10) A pharmacy technician may perform the delegated acts authorized by this section at a remote-site pharmacy under the remote supervision of a licensed supervising pharmacist as defined in s. 465.0198. A licensed supervising pharmacist may not remotely supervise more than six registered pharmacy technicians.

Section 3. Section 465.0198, Florida Statutes, is created to read:

465.0198 Remote-site pharmacy permits.—

(1) As used in this section, the term:

(a) "Supervising pharmacist" means a pharmacist licensed in this state employed by or under contract with a pharmacy licensed in this state who remotely supervises registered pharmacy technicians at a remote-site pharmacy.

(b) "Supervising pharmacy" means a pharmacy licensed in this state which employs or contracts with a pharmacist licensed in this state to serve as the supervising pharmacist for a remote-site pharmacy that is jointly owned by or operated under a contract with the pharmacy.

(2) Any person desiring a permit to operate a remote-site pharmacy must apply to the department. If the board certifies that the application complies with the laws and rules of the board, the department must issue the permit. A permit may not be issued unless a licensed pharmacist or consultant pharmacist is designated as the prescription department manager responsible for the oversight of the remote-site pharmacy. The permittee must notify the department within 10 days after any change of the prescription department manager.

(3) A remote-site pharmacy must comply with all of the following:

(a) Be jointly owned by or operated under a contract with a supervising pharmacy.

(b) Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days.

(c) Display a sign visible to the public indicating that the location is a remote-site pharmacy and that the facility is under 24-hour video surveillance.

(d) Maintain a policies and procedures manual, which must be made available to the board or its agent upon request and must include, but need not be limited to, all of the following:

1. A description of how the pharmacy will comply with federal and state laws and rules.

2. The procedures for supervising the remote-site pharmacy and counseling its patients.

3. The procedures for reviewing the prescription drug inventory and drug records maintained by the remote-site pharmacy.

4. The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.

5. The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote-site pharmacy's operation.

6. The procedures for use of the state prescription drug monitoring program by the prescription department manager before he or she may authorize the dispensing of any controlled substance.

7. The procedures for maintaining a perpetual inventory of the controlled substances listed in Schedule II of s. 893.03.

8. The specific duties, tasks, and functions that

registered pharmacy technicians are authorized to perform at the remote-site pharmacy.

(4) A remote-site pharmacy may store, hold, or dispense any medicinal drug, including proprietary drugs and controlled substances. However, a remote-site pharmacy may not dispense Schedule II controlled substances listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

(5) The prescription department manager must visit the remote-site pharmacy, based on a schedule determined by the board, to inspect the pharmacy, address personnel matters, and provide clinical services for patients.

(6) A remote-site pharmacy may not be open when the supervising pharmacy is closed, unless a supervising pharmacist is present at the remote-site pharmacy or is providing remote supervision as required under this section.

(7) The board may adopt rules necessary to specify additional criteria for a remote-site pharmacy related to:

(a) Application requirements.

(b) Structural and equipment requirements.

(c) Training requirements.

(d) Inventory recordkeeping and storage requirements.

Section 4. Paragraph (c) of subsection (11) of section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.—

(11) A permittee must notify the department of the identity of the prescription department manager within 10 days

after employment. The prescription department manager must comply with the following requirements:

(c) A registered pharmacist may not serve as the prescription department manager in more than one location, except as authorized under s. 465.0198, unless approved by the board.

Section 5. This act shall take effect July 1, 2024.

T I T L E A M E N D M E N T

Remove everything before the enacting clause and insert: An act relating to pharmacy; amending s. 465.003, F.S.; revising the definition of the term "pharmacy" to include remote-site pharmacies; revising construction of the term "not present and on duty"; amending s. 465.014, F.S.; authorizing registered pharmacy technicians to perform delegated tasks at a remote-site pharmacy under remote supervision; establishing the maximum number of registered pharmacy technicians that a pharmacist can remotely supervise; creating s. 465.0198, F.S.; defining the terms "supervising pharmacist" and "supervising pharmacy"; providing for the permitting of remote-site pharmacies; requiring a licensed or consultant pharmacist to serve as the prescription department manager of a remote-site pharmacy; requiring remote-site pharmacies to notify the Department of Health of a change in the pharmacy's prescription department

manager within a specified timeframe; providing requirements for remote-site pharmacies; authorizing remote-site pharmacies to store, hold, and dispense medicinal drugs; prohibiting the dispensing of Schedule II medications at remote-site pharmacies unless a pharmacist is present; requiring prescription department managers to visit remote-site pharmacies, based on a certain schedule, to perform specified tasks; prohibiting remote-site pharmacies from being open when the supervising pharmacy is closed unless a certain pharmacist is present or providing remote supervision at the remote-site pharmacy; authorizing the Board of Pharmacy to adopt specified rules; amending s. 465.022, F.S.; exempting registered pharmacists serving as prescription department managers for remote-site pharmacies from certain practice limitations; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 499 Congenital Cytomegalovirus Screenings
SPONSOR(S): Melo
TIED BILLS: **IDEN./SIM. BILLS:** SB 168

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Cytomegalovirus (CMV) is a common virus that infects people of all ages. Over half of adults are infected with CMV by age 40, and approximately one of every 200 babies is born with congenital CMV (CCMV). Some infants with CCMV infection have health problems that are apparent at birth or that develop later during infancy or childhood. About one in five babies with CCMV have long-term health problems, including hearing loss.

Florida's Newborn Screening Program (NSP), operated by the Department of Health (DOH), screens all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, including hearing loss. In the event that a newborn screen has an abnormal result, the baby's health care provider, or a nurse or specialist from NSP's Follow-up Program provides follow-up services and referrals for the child and his or her family.

Current law requires all newborns be screened for hearing loss at birth, unless such screening is objected to by the newborn's parent or guardian; newborns who fail the hearing screening must also be screened for CCMV. In 2021, 8,500 newborns did not pass their hearing screening, of which, 300 were diagnosed with hearing loss.

The bill expands the population which must undergo mandatory CCMV testing beyond the current population of infants who fail the required newborn hearing screening to include infants admitted to a neonatal intensive care unit within 21 days of birth for specified reasons, and newborns who are transferred to another facility for a higher level of care.

The bill also requires that children diagnosed with a congenital cytomegalovirus infection, with or without hearing loss, be referred to the Children's Medical Services Early Intervention Program and be deemed eligible for a baseline evaluation and any medically necessary follow-up reevaluations and monitoring.

The bill has an significant, negative fiscal impact on the Department of Health, and no fiscal impact on local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Newborn Screening Program

The Legislature created the Florida Newborn Screening Program (NSP) within the Department of Health (DOH), to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[1] The NSP also promotes the identification and screening of all newborns in the state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services.[2]

The NSP involves coordination across several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (state laboratory), DOH Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, and referral centers, birthing centers, and physicians throughout the state.[3] Health care providers in hospitals, birthing centers, perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NSP screening process.[4] This includes a risk assessment for prenatal women, and risk factor analysis and screening for postnatal women and newborns as well as laboratory screening for select disorders in newborns.[5] The NSP attempts to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for select disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[6] The NSP is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[7]

Health care providers perform non-laboratory NSP screening, such as hearing and risk factor analysis, and report the results to the Office of Vital Statistics. If necessary, health care providers refer patients to the appropriate health, education, and social services.[8] Health care providers in hospitals and birthing centers perform specimen collection for laboratory NSP screening by collecting a few drops of blood from the newborn's heel on a standardized specimen collection card.[9] The specimen card is then sent to the state laboratory for testing and the results are released to the newborn's health care provider. In the event that a newborn screen has an abnormal result, the baby's health care provider, or a nurse or specialist from NSP's Follow-up Program provides follow-up services and referrals for the child and his or her family.[10]

To administer the NSP, DOH is authorized to charge and collect a fee not to exceed $15 per live birth occurring in a hospital or birth center.[11] DOH must calculate the annual assessment for each hospital and birth center, and then quarterly generate and mail each hospital and birth center a statement of the

[1] S. 383.14(1), F.S.
[2] *Id*.
[3] S. 383.14, F.S.
[4] *Id.*
[5] *Id*.
[6] Florida Department of Health, *Florida Newborn Screening Guidelines*. Available at https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited January 26, 2024).
[7] S. 383.14(4), F.S.; Rule 64C-7.008, F.A.C.; The health care provider must attempt to get a written statement of objection to be placed in the medical record.
[8] *Id*.
[9] Florida Newborn Screening, *What is Newborn Screening?* Available at https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited January 26, 2024). *See also,* Florida Newborn Screening, *Specimen Collection Card*, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited January 26, 2024).
[10] *Id*.
[11] S. 383.145(3)(g)1., F.S.

amount due.[12] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[13] DOH is authorized to bill third-party payers for the NSP tests and bills insurers directly for the cost of the screening.[14] DOH does not bill families that do not have insurance coverage.[15]

The Legislature established the Florida Genetics and Newborn Screening Advisory Council to advise DOH on disorders to be included in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[16] Florida's NSP currently screens for 58 conditions, 55 of which are screened through the collection of blood spots. Screening of the other three conditions—hearing screening, critical congenital heart defect (CCHD) or pulse oximetry, and congenital cytomegalovirus (CCMV) targeted screening—are completed at the birthing facility through point of care (POC) testing.[17]

Congenital Cytomegalovirus

Cytomegalovirus (CMV) is a common virus for people of all ages; however, a healthy person's immune system usually keeps the virus from causing illness.[18] In the United States, nearly one in three children are infected with CMV by age five. Over half of adults have been infected with CMV by age 40. Once CMV is in a person's body, it stays there for life and can reactivate. A person can also be re-infected with a different strain of the virus. Most people with CMV infection have no symptoms and aren't aware that they have been infected.[19]

CMV that is present in a newborn at birth is known as congenital CMV (CCMV). Congenital CMV occurs when the virus is present in a pregnant woman's blood and crosses the placenta to the fetus. This can happen if a woman is infected with CMV for the first time while she is pregnant, or is infected with CMV again during pregnancy.[20] In the most severe cases, a CMV infection can cause a woman to lose her pregnancy.

Some infants with CCMV infection have health problems that are apparent at birth or that develop later during infancy or childhood. CCMV is the most common infectious cause of birth defects in the United States; approximately one in 200 infants are born with CCMV.[21] Infants with CCMV infection may have signs at birth, which include:[22]

- Rash;
- Jaundice (yellowing of the skin or whites of the eyes);
- Microcephaly (small head);
- Low birth weight;
- Hepatosplenomegaly (enlarged liver and spleen);
- Seizures; and
- Retinitis (damaged eye retina).

Infants with signs of CCMV infection at birth may have long-term health problems, such as:[23]

- Hearing loss;

[12] *Id.*
[13] S. 383.145(3)(g), F.S.
[14] S. 383.145(3)(h), F.S.
[15] *Supra*, note 3.
[16] S. 383.14(5), F.S.
[17] Department of Health, *Agency Analysis of HB 499* (2024). On file with the Healthcare Regulation Subcommittee.
[18] Centers for Disease Control and Prevention. *About Cytomegalovirus (CMV)*. Available at https://www.cdc.gov/cmv/overview.html (last visited January 26, 2024).
[19] *Id.*
[20] Centers for Disease Control and Prevention. *Babies Born with Congenital Cytomegalovirus (CMV)*. Available at https://www.cdc.gov/cmv/congenital-infection.html, (last visited January 26, 2024).
[21] Centers for Disease Control and Prevention. *CMV Fact Sheet for Healthcare Providers*. Available at https://www.cdc.gov/cmv/fact-sheets/healthcare-providers.html#:~:text=Cytomegalovirus%20(CMV)%20is%20the%20most,Hearing%20loss (last visited January 26, 2024).
[22] *Supra,* note 20.
[23] *Id.*

- Developmental and motor delay;
- Vision loss;
- Microcephaly (small head); and
- Seizures.

One out of five infants with CCMV will have symptoms or long-term health problems, such as hearing loss. Approximately 15% of infants with CCMV will not have signs at birth, but will later develop hearing loss.[24] Infants may have hearing loss that may or may not be detected by newborn hearing test. Hearing loss may be present at birth or may develop later, even in infants who passed the newborn hearing test.[25] Hearing loss may progress from mild to severe during the first two years of life, which is a critical period for language learning. Over time, hearing loss can affect a child's ability to develop communication, language, and social skills.[26]

CCMV infection is diagnosed by detection of CCMV DNA in the urine, saliva (preferred specimens), or blood, within three weeks after birth. Infection cannot be diagnosed using tests that detect antibodies to CCMV. CCMV infection cannot be diagnosed using samples collected more than three weeks after birth because testing after this time cannot distinguish between congenital infection and an infection acquired during or after delivery.[27] Infants who show signs of CCMV disease can be treated with medicines called antivirals. Antivirals may decrease the severity of hearing loss. Infants who get treated with antivirals should be closely monitored by their doctor for possible side effects.[28]

CCMV and the Newborn Screening Program

Section 383.145, F.S., requires a newborn hearing screening for all newborns in hospitals before discharge. Before a newborn is discharged from a hospital or other state-licensed birthing facility, and unless objected to by the parent or legal guardian, the newborn must be screened for the detection of hearing loss to prevent the consequences of unidentified disorders.[29]

In 2022, the Legislature enacted a law to provide additional testing requirements for hearing loss in newborns.[30] Under current law, if a newborn fails the hearing screening, the hospital or birthing facility is required to administer an FDA-approved test, or other diagnostically equivalent test, on the newborn to screen for CCMV. The CCMV test must be administered before 21 days of age or before discharge, whichever occurs earlier.[31]

For births occurring in a non-hospital setting, specifically a licensed birth center or private home, the facility or attending health care provider is responsible for providing a referral to an audiologist, a hospital, or other newborn hearing screening provider within 7 days after the birth or discharge from the facility.[32] All screenings must be conducted by a licensed audiologist, a licensed physician, or appropriately supervised individual who has completed documented training specifically for newborn hearing screening.[33] When ordered by the treating physician, screening of a newborn's hearing must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the United States Food and Drug Administration (FDA).[34]

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[24] *Supra*, note 21.
[25] *Id.*
[26] Centers for Disease Control and Prevention. *CMV Fact Sheet for Healthcare Providers*. Available at https://www.cdc.gov/cmv/fact-sheets/healthcare-providers.html#:~:text=Cytomegalovirus%20(CMV)%20is%20the%20most,Hearing%20loss (last visited January 26, 2024).
[27] Centers for Disease Control and Prevention. *About Cytomegalovirus (CMV).* Available at https://www.cdc.gov/cmv/overview.html (last visited January 26, 2024).
[28] Centers for Disease Control and Prevention. *Congenital CMV and Hearing Loss*. Available at https://www.cdc.gov/cmv/hearing-loss.html, (last visited January 26, 2024).
[29] S. 383.145(3), F.S. If the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 21 days after the birth.
[30] Ch. 2022-25, Laws of Fla.
[31] S. 383.145(3)(a), F.S.
[32] S. 383.145(3)(d), F.S.
[33] S. 383.145(3)(f), F.S.
[34] S. 383.145(3)(i), F.S.

If an infant born in a licensed birth center or private home fails the hearing screening, the infant's primary care provider must refer the infant for the administration of an FDA-approved test, or other diagnostically equivalent test, on the newborn to screen for CCMV.[35]

A child who is diagnosed as having a permanent hearing impairment must be referred by the licensee or individual who conducted the screening to the primary care physician for medical management, treatment, and follow-up services. Furthermore, any child from birth to 36 months of age who is diagnosed as having a hearing impairment that requires ongoing special hearing services must be referred to the Children's Medical Services Early Intervention Program by the licensee or individual who conducted the screening serving the geographical area in which the child resides.

In 2021, 8,500 newborns did not pass their hearing screenings and 300 were diagnosed with hearing loss.[36]

Effect of the Bill

The bill expands the population which must undergo mandatory CCMV testing beyond the current population of infants who fail the required newborn hearing screening to include infants admitted to a neonatal intensive care unit within 21 days of birth for any of the following reasons:

- Premature birth prior to 33 weeks gestation;
- Low birth weight;
- Cardiac care; or
- Medical or postsurgical treatment with an anticipated hospital stay greater than three weeks.

The bill requires that infants who must be transferred to another facility for a higher level of care be tested for CCMV and requires the birthing hospital initiate the CCMV testing before transferring the infant. Infants who are admitted or transferred for intensive or prolonged care must be screened for CCMV regardless of whether they have failed a hearing screening.

The bill also requires that children diagnosed with a congenital cytomegalovirus infection, with or without hearing loss, be referred to the Children's Medical Services Early Intervention Program and be deemed eligible for a baseline evaluation and any medically necessary follow-up reevaluations and monitoring.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 383.145, F.S., relating to newborn and infant hearing screenings.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

[35] S. 383.145(3)(e), F.S.
[36] *Supra* note 18.

The bill has a significant, negative fiscal impact on DOH due to the increase in workload for the NBHS program. DOH anticipates the need to hire one new FTE to support follow-up for the additional CCMV tests which would be necessitated by the provisions of the bill.[37]

DOH anticipates that the Early Steps Program, the Children's Medical Services Early Intervention Program, would require increased Federal Grants trust fund authority of approximately $917,490 annually.[38]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Medicaid, private insurers, and families would be billed for the CCMV tests. The estimated cost for CCMV testing by urine polymerase chain reaction range from $69 to $346 per test. Hospitals, birthing facilities, and primary care providers could also incur the cost for additional testing supplies and equipment if they are not equipped to test for CCMV.[39]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

[37] *Supra*, note 17.
[38] *Id*.
[39] Department of Health, *Agency Analysis of HB 435* (2023). On file with the Healthcare Regulation Subcommittee.

A bill to be entitled

An act relating to congenital cytomegalovirus screenings; amending s. 383.145, F.S.; requiring certain hospitals to administer congenital cytomegalovirus screenings on newborns admitted to the hospital under specified circumstances; requiring that the screenings be initiated within a specified timeframe; providing construction; providing coverage under the Medicaid program for the screenings and any medically necessary follow-up reevaluations; requiring that newborns diagnosed with congenital cytomegalovirus be referred to a primary care physician for medical management, treatment, and follow-up services; requiring that children diagnosed with a congenital cytomegalovirus infection without hearing loss be referred to the Children's Medical Services Early Intervention Program and be deemed eligible for evaluation and any medically necessary follow-up reevaluations and monitoring under the program; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraphs (a), (k), and (l) of subsection (3) of section 383.145, Florida Statutes, are amended to read:

383.145 Newborn and infant hearing screening.—

(3) REQUIREMENTS FOR SCREENING OF NEWBORNS; INSURANCE COVERAGE; REFERRAL FOR ONGOING SERVICES.—

(a)1. Each hospital or other state-licensed birthing facility that provides maternity and newborn care services shall ensure that all newborns are, before discharge, screened for the detection of hearing loss to prevent the consequences of unidentified disorders. If a newborn fails the screening for the detection of hearing loss, the hospital or other state-licensed birthing facility must administer a test approved by the United States Food and Drug Administration or another diagnostically equivalent test on the newborn to screen for congenital cytomegalovirus before the newborn becomes 21 days of age or before discharge, whichever occurs earlier.

2. Each hospital that provides neonatal intensive care services shall administer a test approved by the United States Food and Drug Administration or another diagnostically equivalent test to screen for congenital cytomegalovirus in each newborn admitted to the hospital as a result of a premature birth occurring before 33 weeks' gestation, due to the newborn's size being small for his or her gestational age, for cardiac care, or for medical or postsurgical treatment requiring an anticipated stay of 3 weeks or longer. Such screening must be initiated before the newborn becomes 21 days of age.

3. If a newborn requires transfer to another hospital for

higher level of care, the birthing hospital must initiate the congenital cytomegalovirus screening before the transfer. For newborns transferred or admitted for intensive and prolonged care, the congenital cytomegalovirus screening must be initiated regardless of whether the newborn failed a hearing screening.

(k) The initial procedures ~~procedure~~ for the congenital cytomegalovirus screening and the hearing screening of the newborn or infant and any medically necessary follow-up reevaluations leading to diagnosis are ~~shall be a~~ covered benefits ~~benefit~~ for Medicaid patients covered by a fee-for-service program. For Medicaid patients enrolled in HMOs, providers must ~~shall~~ be reimbursed directly by the Medicaid Program Office at the Medicaid rate. This service is ~~may~~ not ~~be~~ considered a covered service for the purposes of establishing the payment rate for Medicaid HMOs. All health insurance policies and health maintenance organizations as provided under ss. 627.6416, 627.6579, and 641.31(30), except for supplemental policies that only provide coverage for specific diseases, hospital indemnity, or Medicare supplement, or to the supplemental policies, must ~~shall~~ compensate providers for the covered benefit at the contracted rate. Nonhospital-based providers are eligible to bill Medicaid for the professional and technical component of each procedure code.

(l) A child ~~who is~~ diagnosed as having permanent hearing loss or a congenital cytomegalovirus infection must be referred

to the primary care physician for medical management, treatment, and follow-up services. Furthermore, in accordance with Part C of the Individuals with Disabilities Education Act, Pub. L. No. 108-446, Infants and Toddlers with Disabilities, any child from birth to 36 months of age ~~who is~~ diagnosed as having hearing loss that requires ongoing special hearing services must be referred to the Children's Medical Services Early Intervention Program serving the geographical area in which the child resides. A child diagnosed with a congenital cytomegalovirus infection without hearing loss must be referred to the Children's Medical Services Early Intervention Program and be deemed eligible for a baseline evaluation and any medically necessary follow-up reevaluations and monitoring.

Section 2. This act shall take effect July 1, 2024.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Melo offered the following:

Amendment

Remove lines 45-52 and insert:

birth occurring before 35 weeks' gestation, for cardiac care, or for medical or surgical treatment requiring an anticipated stay of 3 weeks or longer. Such screening must be initiated before the newborn becomes 21 days of age.

3. If a newborn requires transfer to another hospital for a higher level of care, the receiving hospital must initiate the congenital cytomegalovirus screening if the screening has not already been performed by the transferring hospital or the birthing facility. For

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 547 Dentistry
SPONSOR(S): Altman
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Board of Dentistry (BOD) with the Department of Health (DOH) regulates dental practice in Florida, including dentists, dental hygienists, and dental assistants under the Dental Practice Act. A dentist is licensed to examine, diagnose, treat, and care for conditions within the human oral cavity and its adjacent tissues and structures. There are currently 17,193 dentists with active licenses to practice in Florida.

Prior to October 2011, the dental licensure examination was developed and administered by the Board and the Department of Health. As of October 1, 2011, Florida stopped administering its own practical and clinical dental examinations, and the American Dental License Examination (ADEX), developed by the American Board of Dental Examiners, Inc., replaced the Florida Diagnostic Skills Examination as Florida's dental licensure exam. The ADEX is administered by the CDCA-WREB-CITA© (CDCA).

Current law includes requirements which are now obsolete as Florida no longer develops or administers it's own dental licensure exam. Current law also specifies that a passing score on the ADEX is only valid for 365 days after the date that the results were published.

Current law requires all applicants for dental licensure who relocate to Florida and apply for dental licensure with ADEX scores obtained in a different state engage in full-time practice during their first year of licensure within the geographical bounds of Florida.

HB 547 significantly revises the dental licensure requirements relating to the dental licensure exam. The bill deletes language which has been made obsolete through the use of a national licensure exam.

The bill also deletes the language making ADEX scores valid for only 365 days after the scores were published. The bill deletes the requirement that out-of-state licensed dentists engage in full-time practice during their first year of licensure within the geographical bounds of Florida.

The bill has an insignificant, negative fiscal impact on DOH, and no fiscal impact on local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Dental Practice in Florida

The Board of Dentistry (BOD) with the Department of Health (DOH) regulates dental practice in Florida, including dentists, dental hygienists, and dental assistants under the Dental Practice Act.[1] A dentist is licensed to examine, diagnose, treat, and care for conditions within the human oral cavity and its adjacent tissues and structures.[2]

There are currently 17,193 dentists with active licenses to practice in Florida. There are 41 out-of-state registered telehealth dentists.[3]

Dental Licensure

Any person wishing to practice dentistry in this state must meet specific education and examination requirements and apply to the Department of Health (DOH) for licensure. The applicant is required to submit two recent photographs with their application and verify the accuracy of their application by oath.[4]

To be eligible for dental licensure, an applicant must apply to the DOH to take and pass the following examinations:[5]

- The American Dental License Examination (ADEX); and
- An examination on Florida laws and rules relating to dentistry.

The American Dental License Examination (ADEX)

Prior to October 2011, the dental licensure examination was developed and administered by the Board and the Department of Health. As of October 1, 2011, Florida stopped administering its own practical and clinical dental examinations, and the American Dental License Examination (ADEX), developed by the American Board of Dental Examiners, Inc., replaced the Florida Diagnostic Skills Examination as Florida's dental licensure exam. The ADEX is inclusive of a comprehensive diagnostic skills examination covering the full scope of the practice of dentistry.[6] The ADEX is administered by the CDCA-WREB-CITA© (CDCA).[7]

The ADEX is administered by the CDCA in two formats: the Curriculum Integrated Format (CIF) and the Traditional Format. The CIF is administered throughout the candidate's third and fourth year of dental school. The Traditional Format is administered during the candidate's fourth year. Due to this type of administration, dental students complete the ADEX prior to applying for licensure.[8] The ADEX examination fee is $2,795.00[9] and is paid directly to the CDCA by the applicant.[10] Current law requires

[1] S. 466.004, F.S.
[2] S. 466.003(3), F.S.
[3] *See*, Department of Health, *License Verification* web search. Available at https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited January 14, 2023).
[4] S. 466.006(1)(b), F.S.
[5] S. 466.006, F.S.
[6] Rule 64B5-2.013, F.A.C.
[7] Department of Health, Agency Bill Analysis for HB 547 (2024). On file with the Healthcare Regulation Subcommittee.
[8] *Supra*, note 7.
[9] CDCA, ADEX Dental: Examination Overview. Available at https://adextesting.org/adex-dental/ (last visited January 31, 2024).
[10] *Supra*, note 7.

DOH to consult with the BOD in planning the times, places, physical facilities, training of personnel, and other arrangements concerning the administration on the examination.[11]

To take the ADEX clinical examination for dentists, an applicant must be at least 18 years of age and:

- Be a graduate of a dental school accredited by the American Dental Association (ADA) Commission on Dental Accreditation (CODA) or its successor entity, if any, or any other dental accrediting entity recognized by the US Department of Education;
- Be a dental student in the final year of a program at an ADA-CODA accredited dental school who has completed all the coursework necessary to prepare the student to perform the clinical and diagnostic procedures required to pass the examinations. A passing score on the examination is valid for 365 days;[12] and
- Have completed Part I and II of the National Board Dental Examination (NBDE), administered by the Joint Commission on National Dental Examinations (JCNDE);[13] or
- Have an active health access dental license in this state; and
    - The applicant has 5,000 hours within four consecutive years of clinical practice experience providing direct patient care in a health access setting; the applicant is a retired veteran dentist of any branch of the US Armed Services who has practiced dentistry while on active duty and has at least 3,000 hours within three consecutive years of clinical practice experience providing direct patient care in a health access setting, or the applicant has provided a portion of his or her salaried time teaching health profession students in any public education setting and has at least 3,000 hours within three consecutive years of clinical practice experience providing direct patient care in a health access setting; and
    - The applicant has not been disciplined by the BOD, except for citation offenses or minor violations;
    - No claim or action for damages for personal injury alleged to have been caused by error, omission, or negligence in the performance of the licensee's professional services has been reported to the Office of Insurance Regulation; and
    - The applicant has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.

A person who has graduated from a dental school that is not accredited by the ADA-CODA, a US Department of Education-recognized dental accrediting entity, or otherwise approved by the BOD, may only sit for the ADEX after they submit proof of the following to the BOD:[14]

- At least two consecutive academic years at a full-time supplemental general dentistry program accredited by the American Dental Association Commission on Dental Accreditation. This program must provide didactic and clinical education at the level of a D.D.S. or D.M.D. program accredited by the ADA-CODA; and
- Successful completion of the National Board Dental Examination (Part I and II).

The BOD will then confirm an applicant's eligibility and notify the CDCA.[15]

Current law specifies that a passing score on the ADEX is only valid for 365 days after the date that the results were published.[16] This may cause issues for licensure applicants who completed the dental school and passed the ADEX both in Florida and out of state. A licensure applicant who graduated from an accredited Florida dental school may have passed the ADEX and then leave the state to complete a

[11] S. 466.006(5), F.S.
[12] S. 466.006(4), F.S.
[13] American Dental Association, Joint Commission on National Dental Examinations, *Upholding Quality Oral Care For All.* Available at https://jcnde.ada.org/ (last visited January 31, 2024).
[14] Florida Board of Dentistry, Dentist – Process. Available at https://floridasdentistry.gov/licensing/dentist/#tab-process (last visited January 31, 2024).
[15] *Id.*
[16] S. 466.006(4), F.S.

residency without first obtaining a Florida dental license. Upon returning to Florida, such person's ADEX scores will be invalid due to the length of time that has passed and the person will be required to take and pass the ADEX again to be eligible for licensure in Florida.[17]

The results of the ADEX administered out-of-state are valid for Florida licensure, however, such exam scores are also only valid for 365 days after the date that the results were published. A licensure applicant who passed the ADEX in another state more than 365 days prior is still eligible for licensure, but must meet the following additional requirements:[18]

- Confirmation that the applicant completed the ADEX examination after October 1, 2011.
- Graduation from a dental school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting organization recognized by the United States Department of Education. If the applicant did not graduate from such a dental school, the applicant may submit proof of having successfully completed a full-time supplemental general dentistry program accredited by the American Dental Association Commission on Dental Accreditation of at least two consecutive academic years at such accredited institution.
- Verification that the applicant currently possesses a valid and active dental license in good standing, with no restriction, which has never been revoked, suspended, restricted, or otherwise disciplined, from another state or territory.
- Submission of proof that the applicant has never been reported to the National Practitioner Data Bank (NPDB), the Healthcare Integrity and Protection Data Bank, or the American Association of Dental Boards Clearinghouse, unless successfully appealed.
- Submission of proof that the applicant has been consecutively engaged in the full-time[19] practice of dentistry in another state or territory in the five years, or since the date of initial licensure if less than five years, immediately preceding the date of application for licensure.

In fiscal year 2022-2023, 175 applicants applied for dental licensure in Florida with ADEX scores issued in another state and older than 365 days. Of the 175 applicants, 127 met the additional requirements to become licensed.[20]

All applicants for dental licensure who relocate to Florida and apply for dental licensure with ADEX scores obtained in a different state, must engage in full-time practice during their first year of licensure within the geographical bounds of Florida. Full-time practice is defined as 1,200 hours. Thirty days prior to the expiration of license, the BOD is required to notify the licensee of the need to comply with the full-time practice requirement. If the BOD does not receive a response, the licensee must be served with a notice of pending expiration and be given 20 days to submit proof of full-time practice. If no response is received or the licensee if unable to prove full time practice, the BOD will enter an administrative order to expire the license.[21]

Continuing Education

Licensed dentists are required to complete at least 30 hours of continuing education (CE) in dental subjects biennially, as a condition of their licensure renewal. A minimum of two hours of CE must be on the safe and effective prescribing of controlled substances. The CE courses must contribute directly to the dental education of the dentist and may include attendance at lectures, study clubs, college postgraduate courses, or scientific sessions of conventions; and research, graduate study, teaching, or service as a clinician. The BOD may authorize up to three hours of CE biennially for a practice

[17] *Supra*, note 7.
[18] S. 466.006(4)(b), F.S.
[19] *See*, S. 466.006(4)(b)2., F.S.; Full-time practice is defined as a minimum of 1,200 hours per year for each year in the consecutive 5-year period or since initial licensure, and must include any combination of the following active clinical practice of dentistry providing direct patient care, full-time practice as a faculty member employed by an accredited dental or dental hygiene school, or full-time practice as a student at an accredited postgraduate dental education program.
[20] *Supra*, note 7.
[21] S. 466.006(6), F.S.

management course that includes principles of ethical practice management, provides substance abuse, effective communication with patients, time management, and burnout prevention instruction.[22]

Effect of the Bill

HB 547 removes the BOD and DOH from the dental licensure examination administration process. The bill deletes obsolete language and codifies the current examination process by removing the following requirements:

- Applicants must apply to DOH to sit for the ADEX, and reapply to retake the exam;
- Applicants must submit two photographs to DOH;
- The BOD must set the examination and reexamination fees.
- DOH must consult with the Board of Dentistry in planning all arrangements concerning the administration of the examination; and
- DOH must conduct a mandatory standardization exercise for all examiners.

These requirements are obsolete due to the administration of the ADEX by CDCA.

Under the bill, an applicant who has passed the ADEX will be eligible for dental licensure upon applying to DOH and demonstrating that the applicant is at least 18 years of age and:

- A graduate of an accredited dental school.
- Has successfully completed the examination administered by the Joint Commission on National Dental Examinations (NDBE).
- Has successfully completed the laws and rules examination

The bill deletes the provision that ADEX scores are only valid for 365 days.

The bill removes language related to an obsolete licensure pathway for full licensure for a Health Access Dentist which does not include passage of the examination of the NBDE. This language is inconsistent with s. 466.0067(6), F.S., which requires all applicants for a Health Access Dental license to have passed the examination of the NBDE.

The bill revises the requirements for an out-of-state applicant to prove their full-time practice history. The bill removes the requirement that an out of state applicant submit their proof of full-time practice under oath with penalties of perjury and the requirement that someone unrelated to the applicant submit an affidavit relating to the applicant's full-time practice. Under the bill, the applicant would instead be required to prove full-time practice by submitting their annual income tax return filed with the Internal Revenue Service.

The bill authorizes the BOD to excuse applicants from the 1,200-hour practice requirement in the event of an unusual circumstance, emergency, or special hardship.

The bill removes the requirement for relocating licensees to engage in full-time practice, defined as a minimum of 1,200 hours, in Florida within one year of receiving such license. By removing this requirement, the licensee would no longer be required to submit documentation to the BOD proving full-time practice.

The bill revises the CE requirements for dentists to allow that the BOD may authorize up to three hours of credit biennially for a practice management course that may include instruction on principles of ethical practice management, provides substance abuse, effective communication with patients, time management, or burnout prevention instruction. This revision clarifies the content of the course and provides than one or more of the listed subjects may be included, as opposed to the current requirement for all of them to be included.

[22] S. 466.0135, F.S.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 466.006, F.S., relating to the examination of dentists.
Section 2: Amends s. 466.009, F.S., relating to reexamination.
Section 3: Amends s. 466.0135, F.S., relating to continuing education; dentists.
Section 4: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has an insignificant, negative fiscal impact on DOH which current agency resources are adequate to absorb.[23]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Sufficient rule-making authority exists to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

[23] Department of Health, *Agency Bill Analysis for HB 547* (2024). On file with the Healthcare Regulation Subcommittee.

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to dentistry; amending s. 466.006, F.S.; deleting the role of the Board of Dentistry in the administration of the licensure examination for dentists; deleting the requirement for the board to establish an examination fee; revising requirements for licensure as a dentist; deleting a time limitation on the validity of certain licensure examination results; conforming provisions to changes made by the act; deleting a requirement that certain applicants for licensure engage in the full-time practice of dentistry inside the geographic boundaries of this state for 1 year after licensure; deleting provisions related to compliance with and enforcement of such requirement; amending s. 466.009, F.S.; conforming a provision to changes made by the act; deleting a board-imposed reexamination fee; amending s. 466.0135, F.S.; revising continuing education requirements for dentists; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (b) of subsection (1), subsection (2), paragraph (b) of subsection (4), and subsections (5) and (6) of section 466.006, Florida Statutes, are amended to read:

466.006 Examination of dentists.—

(1)

(b) Any person desiring to be licensed as a dentist must ~~shall~~ apply to the department ~~to take the licensure examinations and shall verify the information required on the application by oath. The application shall include two recent photographs~~. There is ~~shall be~~ an application fee set by the board which may not ~~to~~ exceed $100 and is ~~which shall be~~ nonrefundable. ~~There shall also be an examination fee set by the board, which shall not exceed $425 plus the actual per applicant cost to the department for purchase of some or all of the examination from the American Board of Dental Examiners or its successor entity, if any, provided the board finds the successor entity's clinical examination complies with the provisions of this section. The examination fee may be refundable if the applicant is found ineligible to take the examinations.~~

(2) The department shall license an applicant who the board certifies meets all of the following criteria ~~shall be entitled to take the examinations required in this section to practice dentistry in this state if the applicant~~:

(a) Is 18 years of age or older.

(b)1. Is a graduate of a dental school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting entity recognized by the United States Department of Education;

or

2. Is a dental student ~~in the final year of a program~~ at ~~such~~ an accredited dental school who has completed all the coursework necessary to prepare the student to perform the clinical and diagnostic procedures required to pass the licensure examinations. ~~With respect to a dental student in the final year of a program at a dental school, a passing score on the examinations is valid for 365 days after the date the examinations were completed.~~ A dental school student who takes the licensure examinations during the student's final year of an approved dental school must graduate ~~have graduated~~ before being certified for licensure pursuant to s. 466.011.

(c)~~1.~~ Has successfully completed the examination administered by the Joint Commission on National Dental Examinations or its successor organization ~~National Board of Dental Examiners dental examination; or~~

~~2. Has an active health access dental license in this state; and~~

~~a. The applicant has at least 5,000 hours within 4 consecutive years of clinical practice experience providing direct patient care in a health access setting as defined in s. 466.003; the applicant is a retired veteran dentist of any branch of the United States Armed Services who has practiced dentistry while on active duty and has at least 3,000 hours within 3 consecutive years of clinical practice experience~~

~~providing direct patient care in a health access setting as defined in s. 466.003; or the applicant has provided a portion of his or her salaried time teaching health profession students in any public education setting, including, but not limited to, a community college, college, or university, and has at least 3,000 hours within 3 consecutive years of clinical practice experience providing direct patient care in a health access setting as defined in s. 466.003;~~

~~b. The applicant has not been disciplined by the board, except for citation offenses or minor violations;~~

~~c. The applicant has not filed a report pursuant to s. 456.049; and~~

~~d. The applicant has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession~~.

(4) Notwithstanding any other provision of law in chapter 456 pertaining to the clinical dental licensure examination or national examinations, to be licensed as a dentist in this state, an applicant must successfully complete both of the following:

(b) A practical or clinical examination, which must be the American Dental Licensing Examination produced by the American Board of Dental Examiners, Inc., or its successor entity, if any, which ~~that~~ is administered in this state, provided that the board has attained, and continues to maintain thereafter,

representation on the board of directors of the American Board of Dental Examiners, the examination development committee of the American Board of Dental Examiners, and such other committees of the American Board of Dental Examiners as the board deems appropriate by rule to assure that the standards established herein are maintained organizationally. ~~A passing score on the American Dental Licensing Examination administered in this state is valid for 365 days after the date the official examination results are published.~~

1. As an alternative to such practical or clinical examination, an applicant may submit scores from an American Dental Licensing Examination previously administered in a jurisdiction other than this state after October 1, 2011, and such examination results are ~~shall be~~ recognized as valid for the purpose of licensure in this state. A passing score on the American Dental Licensing Examination administered out of state is ~~shall be~~ the same as the passing score for the American Dental Licensing Examination administered in this state. ~~The examination results are valid for 365 days after the date the official examination results are published.~~ The applicant must have completed the examination after October 1, 2011. This subparagraph may not be given retroactive application.

2. If the date of an applicant's passing American Dental Licensing Examination scores from an examination previously administered in a jurisdiction other than this state under

subparagraph 1. is older than 365 days, such scores are nevertheless valid for the purpose of licensure in this state, but only if the applicant demonstrates that all of the following additional standards have been met:

a. The applicant completed the American Dental Licensing Examination after October 1, 2011. This sub-subparagraph may not be given retroactive application.~~;~~

b. The applicant graduated from a dental school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting organization recognized by the United States Department of Education. Provided, however, if the applicant did not graduate from such a dental school, the applicant may submit proof of having successfully completed a full-time supplemental general dentistry program accredited by the American Dental Association Commission on Dental Accreditation of at least 2 consecutive academic years at such accredited sponsoring institution. Such program must provide didactic and clinical education at the level of a D.D.S. or D.M.D. program accredited by the American Dental Association Commission on Dental Accreditation. For purposes of this sub-subparagraph, a supplemental general dentistry program does not include an advanced education program in a dental specialty.~~;~~

c. The applicant currently possesses a valid and active dental license in good standing, with no restriction, which has

never been revoked, suspended, restricted, or otherwise disciplined, from another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.~~;~~

d. The applicant must disclose to the board during the application process if ~~submits proof that~~ he or she has ~~never~~ been reported to the National Practitioner Data Bank, the Healthcare Integrity and Protection Data Bank, or the American Association of Dental Boards Clearinghouse. This sub-subparagraph does not apply if the applicant successfully appealed to have his or her name removed from the data banks of these agencies.~~;~~

e.(I)(A) The applicant submits proof of having been consecutively engaged in the full-time practice of dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico in the 5 years immediately preceding the date of application for licensure in this state; or

(B) If the applicant has been licensed in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico for less than 5 years, the applicant submits proof of having been engaged in the full-time practice of dentistry since the date of his or her initial licensure.

(II) As used in this section, "full-time practice" is defined as a minimum of 1,200 hours per year for each ~~and every~~

year in the consecutive 5-year period or, when applicable, the period since initial licensure, and must include any combination of the following:

(A) Active clinical practice of dentistry providing direct patient care.

(B) Full-time practice as a faculty member employed by a dental or dental hygiene school approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(C) Full-time practice as a student at a postgraduate dental education program approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(III) The board shall develop rules to determine what type of proof of full-time practice is required and to recoup the cost to the board of verifying full-time practice under this section. Such proof must, at a minimum, be:

(A) Admissible as evidence in an administrative proceeding;

(B) Submitted in writing;

(C) ~~Submitted by the applicant under oath with penalties of perjury attached;~~

~~(D)~~ Further documented by an applicant's annual income tax return filed with the Internal Revenue Service for each year in the preceding 5-year period or, if the applicant has been

practicing for less than 5 years, the period since initial licensure ~~affidavit of someone unrelated to the applicant who is familiar with the applicant's practice and testifies with particularity that the applicant has been engaged in full-time practice~~; and

(D)~~(E)~~ Specifically found by the board to be both credible and admissible.

(IV) The board may excuse applicants from the 1,200-hour requirement in the event of hardship, as defined by the board. ~~An affidavit of only the applicant is not acceptable proof of full-time practice unless it is further attested to by someone unrelated to the applicant who has personal knowledge of the applicant's practice. If the board deems it necessary to assess credibility or accuracy, the board may require the applicant or the applicant's witnesses to appear before the board and give oral testimony under oath;~~

f. The applicant submits documentation that he or she has completed, or will complete before he or she is licensed in this state, continuing education equivalent to this state's requirements for the last full reporting biennium.~~;~~

g. The applicant proves that he or she has never been convicted of, or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession in any jurisdiction.~~;~~

h. The applicant has successfully passed a written

examination on the laws and rules of this state regulating the practice of dentistry and the computer-based diagnostic skills examination.~~; and~~

i. The applicant submits documentation that he or she has successfully completed the applicable examination administered by the Joint Commission on National Dental Examinations or its successor organization.

(5)(a) The practical examination required under subsection (4) is the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc., or its successor entity, if any, provided the board finds that the successor entity's clinical examination complies with the provisions of this section, and must include, at a minimum, all of the following:

1. A comprehensive diagnostic skills examination covering the full scope of dentistry and an examination on applied clinical diagnosis and treatment planning in dentistry for dental candidates.~~;~~

2. Two restorations on a manikin that has typodont teeth with simulated caries as approved by the Commission on Dental Competency Assessments. The board by rule shall determine the class of such restorations.~~;~~

3. A demonstration of periodontal skills on a manikin that has typodont teeth with simulated calculus as approved by the Commission on Dental Competency Assessments.~~;~~

4. A demonstration of prosthetics and restorative skills in complete and partial dentures and crowns and bridges and the utilization of practical methods of evaluation, specifically including the evaluation by the candidate of completed laboratory products such as, but not limited to, crowns and inlays filled to prepared model teeth.~~;~~

5. A demonstration of restorative skills on a manikin which requires the candidate to complete procedures performed in preparation for a cast restoration.~~;~~

6. A demonstration of endodontic skills.~~; and~~

7. A diagnostic skills examination demonstrating ability to diagnose conditions within the human oral cavity and its adjacent tissues and structures from photographs, slides, radiographs, or models pursuant to rules of the board. If an applicant fails to pass the diagnostic skills examination in three attempts, the applicant is not eligible for reexamination unless she or he completes additional educational requirements established by the board.

(b) ~~The department shall consult with the board in planning the times, places, physical facilities, training of personnel, and other arrangements concerning the administration of the examination. The board or a duly designated committee thereof shall approve the final plans for the administration of the examination;~~

~~(c)~~ If the applicant fails to pass the clinical

examination in three attempts, the applicant is ~~shall~~ not ~~be~~ eligible for reexamination unless she or he completes additional educational requirements established by the board.~~; and~~

(c)~~(d)~~ The board may by rule provide for additional procedures that ~~which~~ are to be tested, provided such procedures are ~~shall be~~ common to the practice of general dentistry. The board by rule shall determine the passing grade for each procedure and the acceptable variation for examiners. ~~No~~ Such rules may not ~~rule shall~~ apply retroactively.

~~The department shall require a mandatory standardization exercise for all examiners prior to each practical or clinical examination and shall retain for employment only those dentists who have substantially adhered to the standard of grading established at such exercise.~~

~~(6)(a) It is the finding of the Legislature that absent a threat to the health, safety, and welfare of the public, the relocation of applicants to practice dentistry within the geographic boundaries of this state, who are lawfully and currently practicing dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, based on their scores from the American Dental Licensing Examination administered in a state other than this state, is substantially related to achieving the important state interest of improving access to dental care for underserved~~

~~citizens of this state and furthering the economic development goals of the state. Therefore, in order to maintain valid active licensure in this state, all applicants for licensure who are relocating to this state based on scores from the American Dental Licensing Examination administered in a state other than this state must actually engage in the full-time practice of dentistry inside the geographic boundaries of this state within 1 year of receiving such licensure in this state. The Legislature finds that, if such applicants do not actually engage in the full-time practice of dentistry within the geographic boundaries of this state within 1 year of receiving such a license in this state, access to dental care for the public will not significantly increase, patients' continuity of care will not be attained, and the economic development goals of the state will not be significantly met.~~

~~(b)1. As used in this section, "full-time practice of dentistry within the geographic boundaries of this state within 1 year" is defined as a minimum of 1,200 hours in the initial year of licensure, which must include any combination of the following:~~

~~a. Active clinical practice of dentistry providing direct patient care within the geographic boundaries of this state.~~

~~b. Full-time practice as a faculty member employed by a dental or dental hygiene school approved by the board or accredited by the American Dental Association Commission on~~

~~Dental Accreditation and located within the geographic boundaries of this state.~~

~~c. Full-time practice as a student at a postgraduate dental education program approved by the board or accredited by the American Dental Association Commission on Dental Accreditation and located within the geographic boundaries of this state.~~

~~2. The board shall develop rules to determine what type of proof of full-time practice of dentistry within the geographic boundaries of this state for 1 year is required in order to maintain active licensure and shall develop rules to recoup the cost to the board of verifying maintenance of such full-time practice under this section. Such proof must, at a minimum:~~

~~a. Be admissible as evidence in an administrative proceeding;~~

~~b. Be submitted in writing;~~

~~c. Be submitted by the applicant under oath with penalties of perjury attached;~~

~~d. Be further documented by an affidavit of someone unrelated to the applicant who is familiar with the applicant's practice and testifies with particularity that the applicant has been engaged in full-time practice of dentistry within the geographic boundaries of this state within the last 365 days;~~ ~~and~~

~~e. Include such additional proof as specifically found by~~

~~the board to be both credible and admissible.~~

~~3. An affidavit of only the applicant is not acceptable proof of full-time practice of dentistry within the geographic boundaries of this state within 1 year, unless it is further attested to by someone unrelated to the applicant who has personal knowledge of the applicant's practice within the last 365 days. If the board deems it necessary to assess credibility or accuracy, the board may require the applicant or the applicant's witnesses to appear before the board and give oral testimony under oath.~~

~~(c) It is the further intent of the Legislature that a license issued pursuant to paragraph (a) shall expire in the event the board finds that it did not receive acceptable proof of full-time practice within the geographic boundaries of this state within 1 year after the initial issuance of the license. The board shall make reasonable attempts within 30 days prior to the expiration of such a license to notify the licensee in writing at his or her last known address of the need for proof of full-time practice in order to continue licensure. If the board has not received a satisfactory response from the licensee within the 30-day period, the licensee must be served with actual or constructive notice of the pending expiration of licensure and be given 20 days in which to submit proof required in order to continue licensure. If the 20-day period expires and the board finds it has not received acceptable proof of full-~~

~~time practice within the geographic boundaries of this state within 1 year after the initial issuance of the license, then the board must issue an administrative order finding that the license has expired. Such an order may be appealed by the former licensee in accordance with the provisions of chapter 120. In the event of expiration, the licensee shall immediately cease and desist from practicing dentistry and shall immediately surrender to the board the wallet-size identification card and wall card. A person who uses or attempts to use a license issued pursuant to this section which has expired commits unlicensed practice of dentistry, a felony of the third degree pursuant to s. 466.026(1)(b), punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

Section 2. Subsection (1) of section 466.009, Florida Statutes, is amended to read:

466.009 Reexamination.—

(1) ~~The department shall permit~~ Any person who fails an examination that ~~which~~ is required under s. 466.006 or s. 466.007 may ~~to~~ retake the examination. ~~If the examination to be retaken is a practical or clinical examination, the applicant shall pay a reexamination fee set by rule of the board in an amount not to exceed the original examination fee.~~

Section 3. Paragraph (c) of subsection (1) of section 466.0135, Florida Statutes, is amended to read:

466.0135 Continuing education; dentists.—

(1) In addition to the other requirements for renewal set out in this chapter, each licensed dentist shall be required to complete biennially not less than 30 hours of continuing professional education in dental subjects, with a minimum of 2 hours of continuing education on the safe and effective prescribing of controlled substances. Programs of continuing education shall be programs of learning that contribute directly to the dental education of the dentist and may include, but shall not be limited to, attendance at lectures, study clubs, college postgraduate courses, or scientific sessions of conventions; and research, graduate study, teaching, or service as a clinician. Programs of continuing education shall be acceptable when adhering to the following general guidelines:

(c) The board may also authorize up to 3 hours of credit biennially for a practice management course that includes instruction on principles of ethical practice management, ~~provides~~ substance abuse, effective communication with patients, time management, or ~~and~~ burnout prevention ~~instruction~~.

Section 4. This act shall take effect July 1, 2024.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1269 Potency for Adult Personal Use of Marijuana
SPONSOR(S): Massullo and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		McElroy	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Delta-9-tetrahydrocannabinol (THC) is the psychoactive chemical in marijuana. The full extent of the health impact of consuming products with high concentration of THC is unknown; however, research indicates that such use significantly increases the risk of marijuana-associated psychosis. Studies have found daily use, especially of high-potency marijuana (over 10 percent THC), is strongly associated with earlier onset of psychosis and the development of schizophrenia in marijuana users. Some studies have also shown that marijuana with a THC concentration of 10 percent or less is effective for medical treatment, including the relief of neuropathic pain and pain caused by conditions such as HIV/AIDS, multiple sclerosis, and post-traumatic surgical pain.

Currently, 24 states and the District of Columbia have legalized the adult use of marijuana. Two states, Connecticut and Vermont, currently have potency limits for adult use marijuana products. Both states prohibit cannabis flower with a total THC concentration greater than 30% and solid or liquid concentrate cannabis products with a total THC concentration of greater than 60% from being cultivated, produced or sold in the adult use market.

Adult personal use of marijuana is not legal in Florida; however, there is a pending ballot initiative to legalize adult personal use. Although Florida does not have an adult personal use program it does have a well-established medical marijuana program, including 25 licensed Medical Marijuana Treatment Centers (MMTC). Currently licensed MMTCs would be eligible to acquire, cultivate, process, manufacture, sell, and distribute adult personal use marijuana products if the ballot initiative were to pass. The THC concentration of the products currently offered by MMTCs varies by the route of administration from .4 percent to 90 percent THC.

HB 1269 establishes THC potency limits for various adult personal use marijuana products. Marijuana in the form for smoking cannot have a THC potency of greater than 10 percent and all other marijuana products, excluding edibles, cannot have a THC potency of greater than 60 percent. Identical to the potency limits in the medical marijuana program, the bill prohibits multi-serving edibles from containing more than 200 mg of THC and a single serving edible from containing more than 10 mg of THC.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of 30 days after passage of an amendment to the State Constitution authorizing adult personal use of marijuana.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Research on the Health Effects of THC

Although there are more than 100 cannabinoids in a marijuana plant, the two main cannabinoids are Delta-9-tetrahydrocannabinol THC and cannabidiol (CBD).[1] THC is a mind-altering chemical that increases appetite and reduces nausea and may also decrease pain, anxiety, and muscle control problems.[2] Though CBD may also have an effect on the mind, it does not produce the high or sense of euphoria associated with THC. CBD has been shown to help with anxiety, depression, reducing pain and inflammation, controlling epileptic seizures, and possibly treating psychosis or mental disorders.[3]

Marijuana has changed over time. The THC concentration in commonly cultivated marijuana plants increased three-fold between 1995 and 2014 (4% and 12% respectively).[4] Conversely, the CBD content decreased from .28% in 2001 to .15% in 2014. In 1995, the level of THC was 14 times higher than its CBD level. In 2014, the THC level was 80 times the CBD level.[5] The marijuana available today is much stronger than previous versions.

Some studies have shown that marijuana with a THC concentration of 10% or less is effective for medical treatment, including the relief of neuropathic pain and pain caused by conditions such as HIV/AIDS, multiple sclerosis, post-traumatic surgical pain.[6] Studies on the use of marijuana for pain relief found that marijuana cigarettes with a THC concentration between 2% and 10% THC provided sufficient pain relief,[7] with one study finding that medium-dose marijuana cigarettes with 3.5% THC were as effective as higher dosed marijuana cigarettes at 7% THC.[8]

A 2014 New England Journal of Medicine study warned that long-term marijuana use can lead to addiction and that adolescents are more vulnerable to adverse long-term outcomes from marijuana use.[9] Specifically, the study found that, as compared with persons who begin to use marijuana in adulthood, those who begin in adolescence are approximately 2 to 4 times as likely to have symptoms of marijuana dependence within 2 years after first use.[10] The study also found that marijuana-based treatments with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.[11]

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[1] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, available at https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know (last visited January 30, 2024).
[2] Healthline, *CBD vs. THC: What's the Difference?*, https://www.healthline.com/health/cbd-vs-thc (last visited January 30, 2024).
[3] *Id*.
[4] *U.S. Surgeon General's Advisory: Marijuana Use and the Developing Brain*, https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html (last visited January 30, 2024).
[5] ElSohly, M.A., Mehmedic, Z., Foster, S., Gon, C., Chandra, S. and Church, J.C. *Changes in Cannabis Potency Over the Last 2 Decades (1995-2014): Analysis of Current Data in the United States,* Biological Psychiatry. April 1, 2016; 79(7):613-619.
[6] Igor Grant,1 J. Hampton Atkinson, Ben Gouaux, and Barth Wilsey. *Medical Marijuana: Clearing Away the Smoke.* Open Neurol J. 2012; 6: 18–25. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358713/; Ellis RJ, Toperoff W, Vaida F, et al. *Smoked Medicinal Cannabis for Neuropathic Pain in HIV: A Randomized, Crossover Clinical Trial,* Neuropsychopharmacology, 2009; 34(3):672-680, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3066045/ (last viewed on January 30, 2024); Abrams DI, Jay CA, Shade SB, et al. *Cannabis in Painful HIV-associated Sensory Neuropathy: A Randomized Placebo-controlled Trial.* Neurology. 2007; 68(7):515-521 available at https://pubmed.ncbi.nlm.nih.gov/17296917/ (last viewed on January 30, 2024); Wilsey B, Marcotte T, Tsodikov A, et al. *A Randomized, Placebo-controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain,* J Pain. 2008;9(6):506-521, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4968043/ (last viewed on January 30, 2024); Wallace M, Schulteis G, Atkinson JH, et al. *Dose-dependent Effects of Smoked Cannabis on Capsaicin-induced Pain and Hyperalgesia in Healthy Volunteers.* Anesthesiology. 2007; 107(5):785–96, available at https://pubs.asahq.org/anesthesiology/article/107/5/785/7080/Dose-dependent-Effects-of-Smoked-Cannabis-on (last viewed on January 30, 2024).
[7] *Id*.
[8] Wilsey B, Marcotte T, Tsodikov A, et al. *A Randomized, Placebo-controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain*. J Pain. 2008; 9(6):506–21, available at https://pubmed.ncbi.nlm.nih.gov/18403272/ (last viewed on January 30, 2024).
[9] Volkow, N.D., Baler, R.D., Compton, W.M. and Weiss, S.R., *Adverse Health Effects of Marijuana Use,* NEW ENG. J. MED., June 5, 2014, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4827335/ (last viewed on January 30, 2024).
[10] *Id*.
[11] *Id*.

Heavy use of marijuana by adolescents is associated with impairments in attention, learning, memory, poor grades, high drop rates and I.Q. reduction.[12] Though the full extent of the health impact of consuming products with high concentration of THC is unknown, research indicates that use of such products significantly increases the risk of marijuana-associated psychosis,[13] regardless of age at first use or the type of marijuana used.[14] A 2019 European study showed that the use of high-potency marijuana (over 10% THC) only modestly increased the odds of a psychotic disorder compared to never using it; however, individuals who started using high-potency marijuana by age 15 showed a doubling of risk.[15] The European study also found that daily use of high-potency cannabis increased the risk of psychotic disorder nearly five times compared with never having used marijuana.[16]

Another study found that frequent use of marijuana or use of marijuana with high THC potency increased the risk of schizophrenia six-fold.[17] According to a literature review of studies on the impact of marijuana use on mental health published in the Journal of the American Medical Association Psychiatry, there is strong physiological and epidemiological evidence supporting a link between marijuana use and schizophrenia.[18] High doses of THC can cause acute, transient, dose-dependent psychosis, which are schizophrenia-like symptoms.[19] Additionally, prospective, longitudinal, and epidemiological studies have consistently found an association between marijuana use and schizophrenia in which marijuana use precedes psychosis, independent of alcohol consumption, and even after removing or controlling for those individuals who had used other drugs.[20]

Even though marijuana use may have been discontinued long before the onset of psychosis, studies have found that the age at which marijuana use begins appears to correlate with the age of onset of psychosis, which suggests that early marijuana use plays a role in initiating psychosis that is independent of actual use.[21] Overall, studies have found that the association between marijuana use and chronic psychosis (including a schizophrenia diagnosis) is stronger in those individuals who have had heavy or frequent marijuana use, use marijuana during adolescence, or use marijuana with high THC potency.[22]

While studies have not shown that marijuana use alone is either necessary or sufficient for the development of schizophrenia, studies suggests that marijuana use may initiate the emergence of a lasting psychotic illness in some individuals, especially those with a genetic vulnerability to develop a psychotic illness.[23]

State Legalization of Adult Use of Marijuana

Currently, 24 states and the District of Columbia have legalized the adult use of marijuana:[24]

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[12] *See* footnote 9; *see also The Influence of Marijuana Use on Neurocognitive Functioning in Adolescents*, Schweinsburg AD, Brown SA, Tapert SF, Curr Drug Abuse Rev. 2008;1(1):99-111, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2825218/ (last viewed on January 30, 2024).

[13] Robin Murray, Harriet Quigley, Diego Quattrone, Amir Englund and Marta Di Forti, *Traditional Marijuana, High-Potency Cannabis and Cannabinoids: Increasing Risk for Psychosis*, World Psychiatry, 2016 Oct; 15(3): 195–204, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5032490/ (last viewed January 30, 2024).

[14] Di Forti et al. *The Contribution of Cannabis Use to Variation in the Incidence of Psychotic Disorder Across Europe (EU-GEI): A Multicenter Case-control Study*. Lancet Psychiatry. 2019; 6:427-36, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7646282/ (last viewed on January 30, 2024); *High-Potency Cannabis and Incident Psychosis: Correcting the Causal Assumption*, The Lancet, Volume 6, Issue 6, June 2019, available at https://doi.org/10.1016/S2215-0366(19)30174-9 (last viewed January 30, 2024); *High-Potency Cannabis and Incident Psychosis: Correcting the Causal Assumption – Author's Reply*, The Lancet, Volume 6, Issue 6, June 2019 available at https://doi.org/10.1016/S2215-0366(19)30176-2 (last viewed January 30, 2024).

[15] *Id*. at 430.

[16] *Id*. at 431. The odds were lower for those who use low-potency marijuana daily.

[17] Nora D. Volkow, MD; James M. Swanson, PhD; A. Eden Evins, MD; Lynn E. DeLisi, MD; Madeline H. Meier, PhD; Raul Gonzalez, PhD; Michael A. P. Bloomfield, MRCPsych; H. Valerie Curran, PhD; Ruben Baler, PhD., *Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review.* JAMA Psychiatry. 2016; 73(3):292-297, available at https://core.ac.uk/reader/79505094?utm_source=linkout (last viewed January 30, 2024).

[18] *Id*.

[19] *Id*.

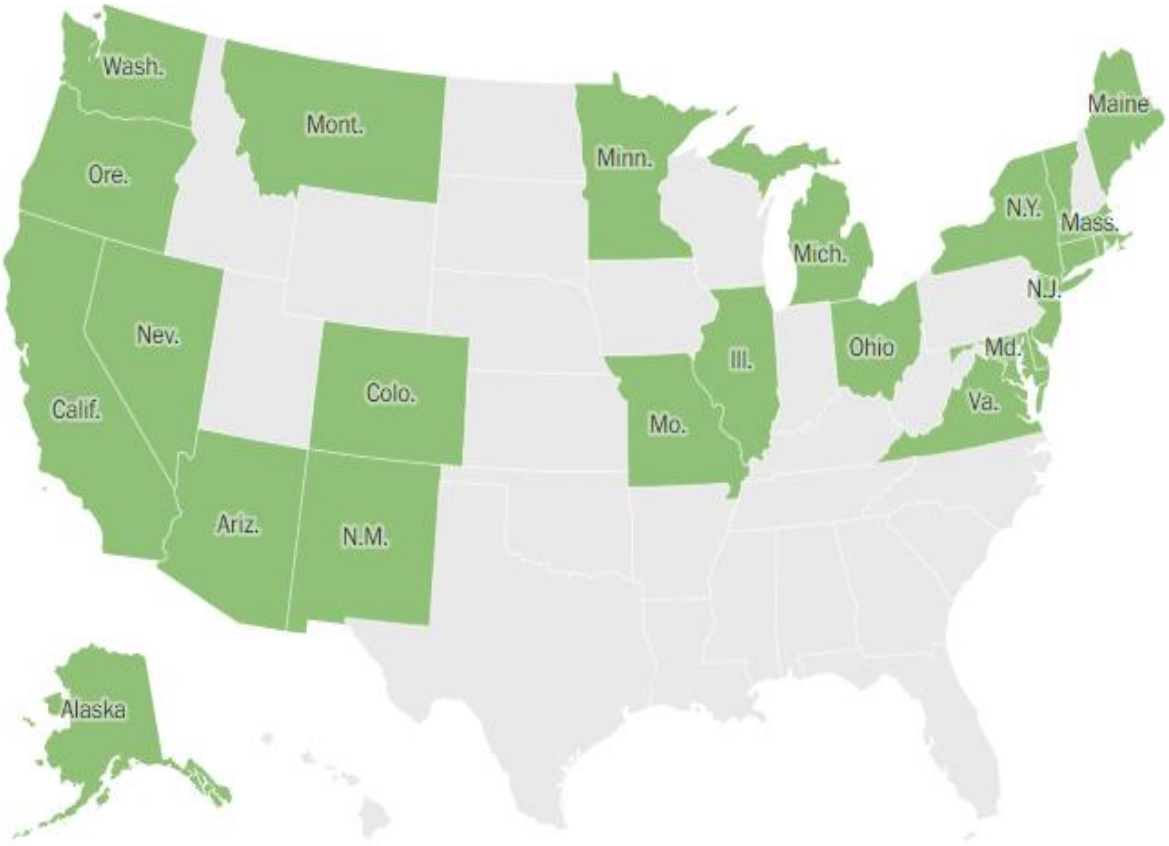
[20] *Id*.

[21] *Id*.

[22] *Id*.

[23] *Id*.

[24] California, Alaska, Nevada, Oregon, Washington, Maine, Colorado, Montana, Vermont, Rhode Island, New Mexico, Michigan, Arizona, New Jersey, Delaware, Connecticut, Massachusetts, Illinois, Maryland, Minnesota, New York, Ohio, Missouri, Virginia.



[25]

State Potency Limits for Adult Use Marijuana

Two states, Connecticut and Vermont, currently have potency limits for adult use marijuana products. Both states prohibit cannabis flower with a total THC concentration greater than 30% and solid or liquid concentrate cannabis products with a total THC concentration of greater than 60% from being cultivated, produced or sold in the adult use market.[26] Both states provided an exception to these potency limits for pre-filled cartridges for vape pens.[27]

Florida - Adult Personal Use of Marijuana

Adult personal use of marijuana is not legal in Florida; however, there is a pending ballot initiative to legalize adult personal use. The proponents of the initiative were required to obtain 891,523 valid signatures to qualify the initiative for the ballot. The proponents have met this requirement as there are currently 1,033,770 valid signatures for the initiative.[28] The ballot summary of the initiative states:[29]

> Allows adults 21 years or older to possess, purchase, or use marijuana products and marijuana accessories for non-medical personal consumption by smoking, ingestion, or otherwise; allows Medical Marijuana Treatment Centers, and other state licensed entities, to acquire, cultivate, process, manufacture, sell, and distribute such products and accessories. Applies to Florida law; does not change, or immunize violations of, federal law. Establishes possession limits for personal use. Allows consistent legislation. Defines terms. Provides effective date.

[25] *More Than Half of Americans Live in Places Where Recreational Marijuana is Legal,* Tim Meko and Adrian Blanco, The Washington Post, Nov. 8, 2023, available at https://www.washingtonpost.com/politics/2023/legal-weed-states-map/ (last viewed January 30, 2024).
[26] See CT ST s. 21a-421j and VT ST T.7 s. 868.
[27] *Id.*
[28] Adult Personal Use of Marijuana 22-05, Florida Division of Elections, available at https://dos.elections.myflorida.com/initiatives/initdetail.asp?account=83475&seqnum=2 (last viewed January 31, 2024).
[29] Constitutional Amendment Full Text, available at https://initiativepetitions.elections.myflorida.com/InitiativeForms/Fulltext/Fulltext_2205_EN.pdf (last viewed January 31, 2024).

The State of Florida requested an advisory opinion from the Florida Supreme Court as to the validity of the initiative specifically seeking guidance on whether the initiative and the ballot title and summary comply with applicable Florida law.[30] Oral arguments occurred in November 2023, and the issue remains pending before the court.[31]

Florida Potency of Medical Marijuana Products

Although Florida does not have an adult personal use program it does have a well-established medical marijuana program. Section 381.986, F.S., authorizes patients with any of the following debilitating medical conditions to obtain medical marijuana from Medical Marijuana Treatment Centers (MMTC):

- Cancer
- Epilepsy
- Glaucoma
- Positive status for human immunodeficiency virus
- Acquired immune deficiency syndrome
- Post-traumatic stress disorder
- Amyotrophic lateral sclerosis
- Crohn's disease
- Parkinson's disease
- Multiple sclerosis
- Medical conditions of the same kind or class as or comparable to those enumerated above

To obtain marijuana for medical use from a Medical Marijuana Treatment Center (MMTC), and maintain the immunity from criminal prosecution, the patient must obtain a physician certification from a qualified physician[32] and an identification card from the Department of Health.

As of January 26, 2024, there are 871,459 qualified patients, 2,781 qualified patients and 25 MMTCs with 618 dispensing locations.[33]

Currently licensed MMTCs would be eligible to acquire, cultivate, process, manufacture, sell, and distribute adult personal use marijuana products if the ballot initiative were to pass. The THC concentration of the products offered by MMTCs varies based on the route of administration as evidenced by the table below.[34]

[30] *Advisory Opinion to the Attorney General Re: Adult Personal Use of Marijuana*, SC2023-0682, 2023, available at https://acis.flcourts.gov/portal/court/68f021c4-6a44-4735-9a76-5360b2e8af13/case/85dca015-d108-4595-8cdb-d4488890aa88 (last viewed January 31, 2024).
[31] *Id.*
[32] To certify patients for medical use of marijuana, a physician must hold an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and comply with certain physician education requirements. See ss. 381.986(1)(m), F.S. and 381.986(3)(a), F.S.
[33] *Office of Medical Marijuana Use Weekly Updates, January 26, 2024,* DOH, Office of Medical Marijuana Use, available at https://knowthefactsmmj.com/wp-content/uploads/ommu_updates/2024/012624-OMMU-Update.pdf (last visited on January 29, 2024).
[34] *Florida's Medical Marijuana Program Update,* Office of Medical Marijuana Use, presented to the Health Care Regulation Subcommittee on December 13, 2023.

Route of Administration	Range in Potency Tetrahydrocannabinol (THC) Content as a Percentage of Volume	
	Lower Threshold	Upper Threshold
Inhalation	60.0%	90.0%
Oral	0.5%	4.0%
Smoking	10.0%	28.0%
Sublingual	0.5%	90.0%
Suppository	1.3%	3.0%
Topical	0.4%	90.0%
Edibles	A multi-serving edible may not contain more than 200 mg of THC, and a single-serving edible, or a single serving portion of a multi-serving edible, may not exceed 10 mg of THC.	

Edibles are the only medical marijuana products currently subject to THC potency limits.

Effect of the Bill

HB 1269 establishes THC potency limits for various adult personal use marijuana products. Marijuana in the form for smoking cannot have a THC potency of greater than 10 percent and all other marijuana products, excluding edibles, cannot have a THC potency of greater than 60 percent. Identical to the potency limits in the medical marijuana program, the bill prohibits multi-serving edibles from containing more than 200 mg of THC and a single serving edible from containing more than 10 mg of THC.

The bill provides an effective date of 30 days after passage of an amendment to the State Constitution authorizing adult personal use of marijuana.

B. SECTION DIRECTORY:

Section 1: Creates s. 381.9861, F.S., relating to the potency limits for adult personal use of marijuana.
Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

A. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

B. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

C. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to potency for adult personal use of marijuana; creating s. 381.9861, F.S.; providing definitions; specifying the authorized potency of tetrahydrocannabinol when consuming marijuana for personal use; providing a contingent effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.9861, Florida Statutes, is created to read:

381.9861 Potency limits for adult personal use of marijuana.—

(1) As used in this section, the term:

(a) "Edibles" means commercially produced food items made with marijuana oil, but no other form of marijuana.

(b) "Marijuana" means all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin, including low-THC cannabis.

(c) "Marijuana delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing marijuana into the human body.

(d) "Personal use" means possession, purchase, or use of marijuana or a marijuana delivery device by an adult 21 years of age or older for nonmedical consumption.

(e) "Potency" means the relative strength of cannabinoids, and the total amount, in milligrams, of tetrahydrocannabinol as the sum of delta-9-tetrahydrocannabinol, plus 0.877 multiplied by tetrahydrocannabinolic acid, plus delta-8-tetrahydrocannabinol and cannabidiol as the sum of cannabidiol, plus 0.877 multiplied by cannabidiolic acid in the final product dispensed to a patient or caregiver.

(2) Marijuana for personal use may not have a tetrahydrocannabinol potency, by weight or volume, of greater than 10 percent for marijuana in a form for smoking or greater than 60 percent in the final product for all other forms of marijuana, excluding edibles. Edibles for personal use may not contain more than 200 milligrams of tetrahydrocannabinol and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol.

Section 2. This act shall take effect 30 days after passage of an amendment to the State Constitution authorizing adult personal use of marijuana.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	_____	

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Massullo offered the following:

Amendment

Remove lines 34-38 and insert:

plus 0.877 multiplied by cannabidiolic acid in the final product.

(2) Marijuana for personal use may not have a tetrahydrocannabinol potency, by weight or volume, of greater than 30 percent for marijuana in a form for smoking or greater

HB 1295

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1295 Health Care Practitioner Titles and Abbreviations
SPONSOR(S): Massullo
TIED BILLS: **IDEN./SIM. BILLS:** SB 1112

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners. The MQA works in conjunction with 22 professional boards and four councils to license and regulate seven types of health care facilities and more than 40 health care professions.

An unlicensed individual may be subject to administrative action or criminal penalties if the individual states or otherwise implies that he or she is a licensed medical professional. This may include the use of certain terms or titles that the public generally associates with a specific medical profession. DOH does not license specialties or sub-specialties based upon board certification, but current law does limit who can hold themselves out as board-certified specialists.

Current law authorizes regulatory boards (or DOH) to discipline health care practitioners for violations related to how they represent their professional identities, including:

- Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession; or
- Failing to identify through writing or orally to a patient the type of license under which the practitioner is practicing.

HB 1295 further regulates the way in which health care practitioners may represent their professions and educational background. The bill specifies the titles and abbreviations that health care practitioners may use in advertisements, communications, and personal identification. Any unauthorized use of a title, abbreviation, or educational degree qualifies as a misleading, deceptive, or fraudulent representation by the health care practitioner and constitutes grounds for discipline.

The bill requires any advertisement for health care services naming a practitioner to identify the practitioner's profession and educational degree. The bill also requires health care practitioners to wear name tags meeting certain requirements, with exceptions. The bill directs each professional board, or DOH if there is no applicable board, to establish rules determining how practitioners must comply with this requirement.

The bill authorizes DOH or the professional boards, as applicable, to discipline any health care practitioner who violates the provisions of the bill.

The bill has an insignificant, negative fiscal impact on DOH, and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Health Care Practitioners Licensure and Regulation

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.[1] The MQA works in conjunction with 22 professional boards and four councils to license and regulate seven types of health care facilities and more than 40 health care professions. Every profession is regulated by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA, as well as a profession- or field-specific practice act which outlines requirements and standards that vary by profession and establishes the individual professional boards.

MQA is statutorily responsible for the following professional boards and advisory councils:[2]

- The Board of Acupuncture, created under ch. 457, F.S.;
- The Board of Athletic Training, created under part XIII of ch. 468, F.S.;
- The Board of Chiropractic Medicine, created under ch. 460, F.S.;
- The Board of Clinical Laboratory Personnel, created under part III of ch. 483, F.S.;
- The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under ch. 491, F.S.;
- The Board of Dentistry, created under ch. 466, F.S.;
- The Board of Hearing Aid Specialists, created under part II of ch. 484, F.S.;
- The Board of Massage Therapy, created under ch. 480, F.S.;
- The Board of Medicine, created under ch. 458, F.S.;
- The Board of Nursing, created under part I of ch. 464, F.S.;
- The Board of Nursing Home Administrators, created under part II of ch. 468, F.S.;
- The Board of Occupational Therapy, created under part III of ch. 468, F.S.;
- The Board of Opticianry, created under part I of ch. 484, F.S.;
- The Board of Optometry, created under ch. 463, F.S.;
- The Board of Orthotists and Prosthetists, created under part XIV of ch. 468, F.S.;
- The Board of Osteopathic Medicine, created under ch. 459, F.S.;
- The Board of Pharmacy, created under ch. 465, F.S.;
- The Board of Physical Therapy Practice, created under ch. 486, F.S.;
- The Board of Podiatric Medicine, created under ch. 461, F.S.;
- The Board of Psychology, created under ch. 490, F.S.;
- The Board of Respiratory Care, created under part V of ch. 468, F.S.;
- The Board of Speech-Language Pathology and Audiology, created under part I of ch. 468, F.S.;
- The Dietetics and Nutrition Practice Council, created under part X of ch. 468, F.S.;
- The Electrolysis Council, created under ch. 478, F.S.;
- The Council of Licensed Midwifery, created under ch. 467, F.S.;
- The Council on Physician Assistants, created under chs. 458 and 459, F.S.

[1] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, mental health counselors, and psychotherapists, among others.

[2] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2022-2022* (2023). Available at https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/MQAAnnualReport2022-2023.pdf (last visited January 26, 2024).

MQA also oversees the following seven health care professions for which there is no profession-specific regulatory board:[3]

- Certified Master Social Workers, as provided by s. 491.015, F.S.;
- Emergency Medical Technicians, as provided under part III of ch. 401, F.S.;
- Genetic Counselors, as provided under part III of ch. 483, F.S.;
- Medical Physicists, as provided under part II of ch. 483, F.S.;
- Naturopaths, as provided under ch. 462, F.S.;[4]
- Paramedics, as provided under part III of ch. 401, F.S.;
- Radiologic Technologists, as provided under part IV under ch. 468, F.S.; and
- School Psychologists, as provided under ch. 490, F.S.

Except for those professions for which there is no board, DOH and the professional boards have different roles in the regulatory system. Boards act as the governing body of a specified profession; they establish practice standards by rule, pursuant to statutory authority and directives, and determine disciplinary action against practitioners who have violated the practice standards.

DOH receives and investigates complaints against practitioners and facilitates the legal response when necessary. DOH, on behalf of the boards, investigates legally sufficient complaints against practitioners.[5] Once an investigation is complete, DOH presents the investigatory findings to the boards. DOH recommends a course of action to the appropriate board's probable cause panel[6] which may include having the file reviewed by an expert, issuing a closing order, or filing an administrative complaint.[7]

The boards determine the course of action and any disciplinary action to take against a practitioner.[8] For professions that have no board, DOH determines the action and discipline to take against a practitioner and issues the final orders.[9] DOH is responsible for ensuring that licensees comply with the terms and penalties imposed by the boards.[10] If a case is appealed, DOH defends the board's (or DOH's) final actions before the appropriate appellate court.[11]

Specialist Board Certification and Florida Licensure

DOH licenses health care practitioners by profession according to the requirements established in statute and rule. DOH does not directly license health care practitioners by specialty or subspecialty; alternatively, current law recognizes the authority of private national specialty boards for granting board certification to practitioners.[12] While DOH does not directly license practitioners by specialty, current law limits which health care practitioners may hold themselves out as board-certified specialists by imposing requirements for specialty designations in individual profession's practice acts.

An allopathic physician (M.D.) may not hold himself or herself out as a board-certified specialist unless he or she has received formal recognition as a specialist from a specialty board of the ABMS or other

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[3] *Id*.
[4] *Id*. There are currently no naturopaths actively licensed to practice in Florida.
[5] Department of Health, *Investigative Services.* Available at http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/isu.html (last visited January 26, 2024).
[6] *See also*, Department of Health, *A Quick Guide to the MQA Disciplinary Process: Probable Cause Panels*. Available at https://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/_documents/a-quick-guide-to-the-mqa-disciplinary-process.pdf (last visited January 26, 2024)
[7] Department of Health, *Prosecution Services.* Available at http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/psu.html (last visited January 26, 2024).
[8] S. 456.072(2), F.S.
[9] *Id*. Professions which do not have a board include naturopathy, nursing assistants, midwifery, respiratory therapy, dietetics and nutrition, electrolysis, medical physicists, and school psychologists.
[10] *Supra*, note 7.
[11] *Id*.
[12] Examples of specialties include dermatology, emergency medicine, ophthalmology, pediatric medicine, certified registered nurse anesthetist, clinical nurse specialist, cardiac nurse, nurse practitioner, endodontics, orthodontics, and pediatric dentistry. Examples of national specialty boards include The American Board of Medical Specialties and The Accreditation Board for Specialty Nursing Certification.

recognizing agency[13] approved by the Board of Medicine.[14] Similarly, an osteopathic physician (D.O.) may not hold himself or herself out as a board-certified specialist unless he or she has successfully completed the requirements for certification by the American Osteopathic Association (AOA) or the Accreditation Council on Graduate Medical Education (ACGME) and is certified as a specialist by a certifying agency[15] approved by the Board of Osteopathic Medicine.[16]

A dentist may not hold himself or herself out as a specialist, or advertise membership in or specialty recognition by an accrediting organization, unless the dentist has completed a specialty education program approved by the American Dental Association and the Commission on Dental Accreditation and the dentist is:[17]

- Eligible for examination by a national specialty board recognized by the American Dental Association; or
- A diplomate of a national specialty board recognized by the American Dental Association.

If a dentist announces or advertises a specialty practice for which there is not an approved accrediting organization, the dentist must clearly state that the specialty is not recognized or that the accrediting organization has not been approved by the American Dental Association or the Florida Board of Dentistry.[18]

By rule, the Board of Chiropractic Medicine (BCM) prohibits chiropractors from using deceptive, fraudulent, and misleading advertising. The BCM permits chiropractors to advertise that they have attained Diplomate status in a chiropractic specialty area recognized by the BCM. BCM-recognized specialties include those which are recognized by the Councils of the American Chiropractic Association, the International Chiropractic Association, the International Academy of Clinical Neurology, or the International Chiropractic Pediatric Association.[19]

Additionally, an advanced practice registered nurse may not advertise or hold himself or herself out as a specialist for which he or she has not received certification.[20]

Professional Identity Representation

Section 456.072, F.S., authorizes a professional board or DOH, if there is no board, to discipline a health care practitioner's licensure for a number of offenses, including but not limited to:

- Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession; or
- Failing to identify through writing or orally to a patient the type of license under which the practitioner is practicing.

Physicians are expressly subject to discipline for advertising a board-certified specialty for which they are not qualified. Using a term designating a medical specialty for which a *non-physician* practitioner has not completed a residency or fellowship program accredited or recognized by the ACGME or the AOA in such specialty is not expressly grounds for discipline under current law.[21]

[13] The Board of Medicine has approved the specialty boards of the ABMS as recognizing agencies. *See,* Rule 64B8-11.001(1)(f), F.A.C.
[14] S. 458.3312, F.S.
[15] The Board of Osteopathic Medicine has approved the specialty boards of the ABMS and AOA as recognizing agencies. *See*, Rule 64B15-14.001(h), F.A.C.
[16] S. 459.0152, F.S.
[17] S. 466.0282, F.S. A dentist may also hold himself or herself out as a specialist if the dentist has continuously held himself or herself out as a specialist since December 31, 1964, in a specialty recognized by the American Dental Association.
[18] S. 466.0282(3), F.S.
[19] Rule 64B-15.001(2)(e), F.A.C. Examples of chiropractic specialties include chiropractic acupuncture, chiropractic internist, chiropractic and clinical nutrition, radiology chiropractic, and pediatric chiropractors.
[20] S. 464.018(1)(s), F.S.
[21] Ss. 458.331(1)(ll) and 459.015(1)(nn), F.S.

If the board or DOH finds that a licensee committed a violation, the board or DOH may:[22]

- Refuse to certify, or to certify with restrictions, an application for a license;
- Suspend or permanently revoke a license;
- Place a restriction on the licensee's practice or license;
- Impose an administrative fine not to exceed $10,000 for each count or separate offense; if the violation is for fraud or making a false representation, a fine of $10,000 must be imposed for each count or separate offense;
- Issue a reprimand or letter of concern;
- Place the licensee on probation;
- Require a corrective action plan;
- Refund fees billed and collected from the patient or third party on behalf of the patient; or
- Require the licensee to undergo remedial education.

Effect of the Bill

Health Care Professional Representation

HB 1295 further regulates the way in which health care practitioners represent their professions.

Professional Designations

The bill specifies the titles and abbreviations that may be used by allopathic and osteopathic physicians, chiropractic physicians, podiatric physicians, dentists, anesthesiologist assistants, and optometrists. Under the bill, health care practitioners, regardless of whether they are specified in the bill, may only identify themselves by the titles and abbreviations authorized by the bill or the practitioner's respective practice act.

Advertisements

Current law authorizes licensure discipline for "deceptive or misleading terms or false representation". The bill expressly makes misrepresentation of a practitioner's educational degree a qualifying offense under this provision.

The bill requires any advertisement for health care services naming a practitioner to identify the practitioner's profession and educational degree as related to the services featured in the advertisement. The advertisement must also include the specific license under which the practitioner is authorized to provide services. These requirements apply to any printed, electronic, or oral statement that:

- Is communicated or disseminated to the general public.
- Is intended to encourage a person to use a practitioner's services or to promote those services or the practitioner in general.
- For commercial purposes, names a practitioner in connection with the practice, profession, or institution in which the practitioner is employed, volunteers, or provides health care services.
- Is prepared, communicated, or disseminated by the practitioner or with their consent.

The bill requires any advertisement by a health care practitioner include the specific license under which they are authorized to provide services, and restricts them to advertising with only the specific titles and abbreviations they are authorized to use under the bill. The bill permits only allopathic or osteopathic physicians, chiropractic physicians, podiatric physicians, and dentists to use the titles, abbreviations, or medical specialties specified in the bill the bill, such as "dermatologist," "oncologist," and "periodontist," in advertisements.

[22] S. 456.073(1), F.S.

Non-physician practitioners may identify themselves according to specialties expressly named in their respective practice acts, but only in conjunction with the title of the profession which they are licensed to practice.

License Display

The bill requires health care practitioners to wear a name tag displaying their name and profession when treating or consulting a patient. The practitioner's profession must be identified on the name tag consistent with the naming conventions specified in the bill. This requirement does not apply to a practitioner providing services in his or her own office if the practitioner prominently displays a copy of his or her license in a conspicuous area of the practice so that it is easily visible to patients.

Discipline

Failure to adhere to the provisions of the bill constitute grounds for discipline. The bill authorizes DOH or the boards, as applicable, to discipline any health care practitioner who violates the preceding requirements. The bill directs each board, or DOH if there is no board, to develop rules determining how practitioners must comply with the requirements of the bill.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0651, F.S., relating to health care practitioner titles and designations.
Section 2: Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
Section 3: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH may experience a non-recurring increase in workload associated with rulemaking, which can be absorbed within current resources.[23] DOH may also experience an increase in workload and costs associated with the enforcement of the provisions of this bill, which can be absorbed within current resources.[24]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

[23] Department of Health, *Agency Analysis of House Bill 583* (2023). (February 7, 2023).
[24] *Id*.

To comply with the provisions of the bill, health care practitioners currently practicing under titles that are not expressly authorized by the bill will need to transition to approved titles. Such practitioners will incur the costs associated with rebranding. The practitioners most likely to be impacted by these requirements are optometrists,[25] commonly identified as optometric physicians, and acupuncturists,[26] commonly referred to as acupuncture physicians and Doctors of Oriental Medicine; such titles are not expressly authorized under the bill, or in the respective practice acts.

Health care practitioners in violation of the restrictions in this bill may be subject to disciplinary actions and fines.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to DOH and the relevant regulatory boards to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

By specifying titles and abbreviations applicable to a specialty or certification, it is unclear if other recognized credentials earned by a health care practitioner may be used. For example, it is unclear if a dentist who has completed advanced training in dental anesthesiology could refer to himself as a dental anesthesiologist.

The DOH analysis of the bill notes that the use of "may" throughout the bill indicates a permissive provision, implying some discretion, which may be difficult to enforce.[27]

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

[25] *See*, Ch. 463, F.S., for the Optometry Practice Act.
[26] See, Ch. 457, F.S., for the statute regulating acupuncture.
[27] *Supra*, note 23.

A bill to be entitled

An act relating to health care practitioner titles and abbreviations; creating s. 456.0651, F.S.; defining terms; providing that, for specified purposes, the use of specified titles or designations in connection with one's name constitutes the practice of medicine or the practice of osteopathic medicine; providing exceptions; amending s. 456.072, F.S.; revising grounds for disciplinary action relating to a practitioner's use of such titles or designations in identifying himself or herself to patients or in advertisements for health care services; revising applicability; requiring certain health care practitioners to prominently display copies of their licenses in a conspicuous area of their practices; requiring that the copy of the license be a specified size; requiring such health care practitioners to also verbally identify themselves in a specified manner to new patients; requiring, rather than authorizing, certain boards or the Department of Health if there is no board, to adopt certain rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.0651, Florida Statutes, is created to read:

456.0651 Health care practitioner titles and designations.—

(1) As used in this section, the term:

(a) "Advertisement" means any printed, electronic, or oral statement that:

1. Is communicated or disseminated to the general public.

2.a. Is intended to encourage a person to use a practitioner's professional services or to promote those services or the practitioner in general; or

b. For commercial purposes, names a practitioner in connection with the practice, profession, or institution in which the practitioner is employed, volunteers, or provides health care services.

3. Is prepared, communicated, or disseminated under the control of the practitioner or with the practitioner's consent.

(b) "Educational degree" means the degree awarded to a practitioner by a college or university relating to the practitioner's profession or specialty designation which may be referenced in an advertisement by name or acronym.

(c) "Misleading, deceptive, or fraudulent representation" means any information that misrepresents or falsely describes a practitioner's profession, skills, training, expertise, educational degree, board certification, or licensure.

(d) "Practitioner" means a health care practitioner as defined in s. 456.001.

(e) "Profession" in addition to the meaning provided in s. 456.001, also means the name or title of a practitioner's profession that is regulated by the department in the Division of Medical Quality Assurance and which is allowed to be used by an individual due to his or her license, license by endorsement, certification, or registration issued by a board or the department. The term does not include a practitioner's license or educational degree.

(2) For purposes of this section and s. 456.065, in addition to the definition of "practice of medicine" in s. 458.305 and the definition of "practice of osteopathic medicine" in s. 459.003, the practice of medicine or osteopathic medicine also includes attaching to one's name, either alone or in combination, or in connection with other words, any of the following titles or designations, if used in an advertisement or in a manner that constitutes a misleading, deceptive, or fraudulent representation:

(a) Doctor of medicine.

(b) M.D.

(c) Doctor of osteopathy.

(d) D.O.

(e) Physician.

(f) Emergency physician.

(g) Family physician.

(h) Interventional pain physician.

(i) Medical doctor.

(j) Osteopath.

(k) Osteopathic physician.

(l) Doctor of osteopathic medicine.

(m) Surgeon.

(n) Neurosurgeon.

(o) General surgeon.

(p) Resident physician.

(q) Medical resident.

(r) Medical intern.

(s) Anesthesiologist.

(t) Cardiologist.

(u) Dermatologist.

(v) Endocrinologist.

(w) Gastroenterologist.

(x) Gynecologist.

(y) Hematologist.

(z) Hospitalist.

(aa) Intensivist.

(bb) Internist.

(cc) Laryngologist.

(dd) Nephrologist.

(ee) Neurologist.

(ff) Obstetrician.

(gg) Oncologist.

(hh) Ophthalmologist.

(ii) Orthopedic surgeon.

(jj) Orthopedist.

(kk) Otologist.

(ll) Otolaryngologist.

(mm) Otorhinolaryngologist.

(nn) Pathologist.

(oo) Pediatrician.

(pp) Primary care physician.

(qq) Proctologist.

(rr) Psychiatrist.

(ss) Radiologist.

(tt) Rheumatologist.

(uu) Rhinologist.

(vv) Urologist.

(3) Notwithstanding subsection (2):

(a) A licensed practitioner may use the name or title of his or her profession which is authorized under his or her practice act, and any corresponding designations or initials so authorized, to describe himself or herself and his or her practice.

(b) A licensed practitioner who has a specialty area of practice authorized under his or her practice act may use the

following format to identify himself or herself or describe his or her practice: "...(name or title of the practitioner's profession)..., specializing in ...(name of the practitioner's specialty)...."

(c) A chiropractic physician licensed under chapter 460 may use the titles "chiropractic physician," "doctor of chiropractic medicine," "chiropractic radiologist," and other titles, abbreviations, or designations authorized under his or her practice act or reflecting those chiropractic specialty areas in which the chiropractic physician has attained diplomate status as recognized by the American Chiropractic Association, the International Chiropractors Association, the International Academy of Clinical Neurology, or the International Chiropractic Pediatric Association.

(d) A podiatric physician licensed under chapter 461 may use the following titles and abbreviations as applicable to his or her license, specialty, and certification: "podiatric physician," "podiatric surgeon," "Fellow in the American College of Foot and Ankle Surgeons," and other titles or abbreviations authorized under his or her practice act.

(e) A dentist licensed under chapter 466 may use the following titles and abbreviations as applicable to his or her license, specialty, and certification: "doctor of medicine in dentistry," "doctor of dental medicine," "D.M.D.," "doctor of dental surgery," "D.D.S.," "oral surgeon," "maxillofacial

surgeon," "oral and maxillofacial surgeon," "O.M.S.," "oral radiologist," "dental anesthesiologist," "oral pathologist," and other titles or abbreviations authorized under his or her practice act.

(f) An anesthesiologist assistant licensed under chapter 458 or chapter 459 may use only the titles "anesthesiologist assistant" or "certified anesthesiologist assistant" and the abbreviation "C.A.A."

(g) An optometrist licensed under chapter 463 may use the following titles and abbreviations as applicable to his or her license, specialty, and certification: "doctor of optometry," "optometric physician," and other titles or abbreviations authorized under his or her practice act.

Section 2. Paragraph (t) of subsection (1) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(t)1. A practitioner's failure, when treating or consulting with a patient, ~~Failing~~ to identify through ~~written notice, which may include~~ the wearing of a name tag the practitioner's name and~~, or orally to a patient~~ the profession, as defined in s. 456.0651, ~~type of license~~ under which the practitioner is practicing. The information on the name tag must

be consistent with the specifications of s. 456.0651(2) such that it does not constitute the unlicensed practice of medicine or osteopathic medicine.

2. The failure of any advertisement for health care services naming the practitioner to ~~must~~ identify the profession, as defined in s. 456.0651, under which the practitioner is practicing and the practitioner's educational degree, as defined in s. 456.0651, in relation to the services featured in the advertisement ~~type of license the practitioner holds~~.

3. Subparagraph 1. ~~This paragraph~~ does not apply to a practitioner while the practitioner is providing services in his or her own office that houses his or her practice or group practice. In such a case, in lieu of a name tag, the practitioner must prominently display a copy of his or her license in a conspicuous area of the practice so that it is easily visible to patients. The copy of the license must be no smaller than the original license. The practitioner must also verbally identify himself or herself to a new patient by name and identify the profession, as defined in s. 456.0651, under which the practitioner is practicing. Such verbal identification must be consistent with the specifications of s. 456.0651(2) such that it does not constitute the unlicensed practice of medicine or osteopathic medicine ~~a facility licensed under chapter 394, chapter 395, chapter 400, or chapter 429~~.

4. Each board, or the department if ~~where~~ there is no board, shall ~~is authorized~~ by rule ~~to~~ determine how its practitioners must ~~may~~ comply with this paragraph ~~disclosure requirement~~.

Section 3. This act shall take effect July 1, 2024.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	_____	

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Massullo offered the following:

Amendment

Remove line 74

HB 1313

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1313 Clinical Laboratory Personnel
SPONSOR(S): Chamberlin
TIED BILLS: **IDEN./SIM. BILLS:** SB 1108

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Guzzo	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Centers for Medicare & Medicaid Services (CMS), within the United States Department of Health and Human Services, regulates all laboratory testing performed on humans in the United States through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The Board of Clinical Laboratory Personnel (Board) within the Department of Health (DOH) oversees the licensure and regulation of clinical laboratory personnel, including directors, supervisors, technologists, technicians, and public health personnel. Licensure requirements for clinical laboratory personnel generally include passage of an exam designated by the Board, completion of a medical technology training program, and completion of applicable education requirements.

All applicants for licensure as a technologist must satisfy the CLIA training and education requirements for High Complexity Testing, and all applicants for licensure as a technician must satisfy the CLIA training and education requirements for Moderate Complexity Testing. In addition, Florida law requires an applicant for licensure as a technologist or technician to comply with additional education and training requirements for each specialty category of licensure.

The bill requires applicants for licensure to perform high or moderate complexity testing as a clinical laboratory technician or technologist to comply only with the federal CLIA education and training requirements. As a result, such applicants will not be required to also comply with the education and training requirements for specialty categories of technician and technologist licensure.

The bill repeals s. 483.811, which authorizes the Board of Clinical Laboratory Personnel to approve clinical laboratory personnel training programs. Training programs will be approved by accrediting organizations authorized under the CLIA. To conform with this change, the bill also removes authority for DOH to conduct exams, register trainers, and approve curriculum in schools and colleges, and removes authority for DOH to collect fees for exams and training programs

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Clinical Laboratory Personnel

A clinical laboratory is a facility in which human specimen is tested to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition.[1] Services performed in clinical labs include the examination of:[2]

- Fluids or other materials taken from the human body;
- Tissue taken from the human body; and
- Cells from individual tissues or fluid taken from the human body.

The Board of Clinical Laboratory Personnel (Board) within the Department of Health (DOH) oversees the licensure and regulation of clinical laboratory personnel, including directors, supervisors, technologists, and technicians.[3] Licensure requirements for clinical laboratory personnel include completion of a medical technology training program,[4] completion of applicable education requirements, and passage of an exam designated by the Board.[5] The Board is authorized to collect fees for initial licensure, licensure renewal, examinations and reexaminations, and providers of laboratory training programs and for trainees of laboratory training programs.[6]

The Board is responsible for approving clinical laboratory training programs in hospitals or clinical laboratories.[7] Any person who completes a training program must also pass an examination provided by DOH.[8]

The federal Centers for Medicare & Medicaid Services (CMS), within the United States Department of Health and Human Services, regulates all laboratory testing performed on humans in the United States through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[9] The CLIA define a clinical laboratory as any facility that examines materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. Any facility that meets this definition must have the appropriate CLIA certificate to perform laboratory tests. If a facility is only collecting specimens, a CLIA certificate is not required.

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[1] S. 483.803(2), F.S.
[2] *Id.*
[3] S. 483.805, F.S.
[4] S. 483.111, F.S., and rule 64B3-3.001, F.A.C., authorize the Board to approve clinical laboratory training programs and requires approved training programs to: designate space and laboratory equipment for proper training of students; maintain a file on each student which contains a completed application, evidence of high school graduation or completion of college courses, attendance records, grades, instructor evaluations of laboratory practice, the trainee's registration, and a copy of the student's certificate of completion or official transcript; maintain current examinations and laboratory evaluation instruments utilized by the program; provide students with a certificate or letter of graduation or a transcript indicating the degree granted. Certificates or letters of graduation must be signed by the program director; include instruction in human immunodeficiency virus and acquired immunodeficiency syndrome; include instruction on the prevention of medical errors, which shall include root-cause analysis, error reduction and prevention, and patient safety; include course objectives, course descriptions, course outlines, assessment of outcomes, student evaluations, and graduate evaluations in the curriculum; utilize educational resources for teaching the affective, cognitive, and psychomotor domains; employ systematic procedures for assessing learning outcomes in the affective, cognitive, and psychomotor domains; have a practicum in a clinical laboratory where current laboratory procedures, instrumentation, and diversity of specimens are available for a variety of analyses and are in sufficient quantity to provide competent training; and include instruction on Florida laws and rules governing clinical laboratories and clinical laboratory personnel.
[5] S. 483.809, F.S.
[6] S. 483.807, F.S.
[7] S. 483.811(4), F.S.
[8] *Id.*
[9] 42 C.F.R. § 493.

Current Florida Law requires applicants for licensure as clinical laboratory personnel to comply with CLIA education and training standards.

Technologists

Clinical laboratory technologists may perform high complexity medical laboratory tests on patient samples including blood, urine, and tissue. Technologists may also interpret clinical laboratory test results.[10] The specialist categories of technologist licensure include: generalist technologist (which includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and immunohematology); blood banking specialist; cytology specialist; cytogenetics specialist; molecular pathology specialist; andrology and embryology specialists; histology specialist; and histocompatibility specialist.

All applicants for licensure as a technologist must satisfy the CLIA requirements for High Complexity Testing, which require the applicant to:[11]

- Be a licensed doctor of medicine, osteopathy, or podiatric medicine; or
- Have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or
- Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution, or have education and training that is equivalent and includes:
    - At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses; and
    - Either completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools or the Committee on Allied Health Education and Accreditation (CAHEA). Or have at least three months of documented laboratory training in each specialty in which the individual performs high complexity testing.

In addition, Florida law requires an applicant for licensure as a technologist to comply with additional education and training requirements for each specialty category of technologist licensure.[12]

Generalist Technologist License

Licensure as a generalist technologist includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and immunohematology. The education, training, and certification requirements for licensure as a generalist technologist include the following:[13]

- A bachelor's degree in clinical laboratory, chemical, or biological science; and
- A clinical laboratory training program approved by the National Accrediting Agency for Clinical Laboratory Science (NAACLS); and
- Certification as a medical laboratory scientist (MLS) or a medical technologist (MT); and
- Pass an examination (the National Registry of Certified Chemists or the national certifying body categorical examinations in a single discipline specialty area.

Or:

- A bachelor's degree in clinical laboratory, chemical, biological science, or a bachelor's degree with 24 semester hours of academic science including six semester hours of biological sciences and six semester hours of chemical sciences; and

[10] Rule 64B3-10.005(2), F.A.C.
[11] Rule 64B3-5.003(2), F.A.C., and 42 C.F.R. § 493.1489.
[12] Rule 64B3-5.003(3), F.A.C.
[13] Rule 64B3-5.003(3)(a), F.A.C.

- A clinical laboratory training program, or three years pertinent clinical laboratory experience with a minimum of six months in each specialty for which licensure is sought; and
- Certification as a MLS or a MT; and
- Pass an examination (the National Registry of Certified Chemists or the national certifying body categorical examinations in a single discipline specialty area.

Or:

- 90 semester hours of college credit with 24 semester hours of academic science, including six semester hours of biological sciences and six semester hours of chemical sciences; and
- A clinical laboratory training program; and
- Certification as a MLS or a MT; and
- Pass a MT examination or a specialist examination in a single discipline specialty area.

Or:

- An associate degree with six semester hours academic biological sciences and six semester hours of academic chemical sciences; and
- A clinical laboratory training program; and
- Certification as a MLS or a MT; and
- Pass a MT examination and a specialist examination in a single discipline specialty area.

Or:

- An associate degree with six semester hours of academic biological sciences and six semester hours of academic chemical sciences; and
- A clinical laboratory training program offered by the Department of Defense; or
    - Five years of pertinent clinical laboratory experience with one year of experience in each specialty area for which licensure is sought; and
- Pass a MT examination and a specialist examination in a single discipline specialty area.

Blood Banking Specialist

A blood banking specialist must:[14]

- Have a bachelor's degree in clinical laboratory, or chemical or biological science; and
- Have a clinical laboratory training program approved by the NAACLS; and
- Be certified in blood banking or as a MLS, MT, or a specialist in blood banking (SBB).

Or:

- Have a bachelor's degree in medical technology with 24 semester hours of academic science, six semester hours of biological science, and six semester hours of chemical science; and
- Be trained as required by the applicable certifying body; and
- Be certified in blood banking or as a MLS, MT, or a SBB.

Or:

- Have a bachelor's degree in clinical laboratory, or chemical or biological science, or a bachelors degree with 24 semester hours of academic science, six semester hours of biological science, and six semester hours of chemical science; and
- Have three years of pertinent clinical laboratory experience; or
    - A clinical laboratory training program; and
- Be certified in blood banking or as a MLS, MT, or a SBB.

[14] Rule 64B3-5.003(3)(b), F.A.C.

Cytology Specialist

A cytology specialist must meet the education and training requirements of the American Society for Clinical Pathology (ASCP).[15]

Cytogenetics Specialist

A cytogenetics specialist must have a bachelor's degree with 30 hours of academic science and complete a board approved training program in cytogenetics at the technologist level or one year of pertinent clinical laboratory experience in cytogenetics. They must also be certified by the ASCP.[16]

Molecular Pathology Specialist

A molecular pathology specialist must:[17]

- Have a bachelor's degree with 16 semester hours of academic science; and
- Complete training as required by the applicable certifying body; and
- Be certified by the ASCP, the American Association of Bioanalysts, the American Board of Histocompatibility and Immunogenetics, or the American Medical Technologists.

Or:

- Meet education standards as required by the applicable certifying body; and
- Have one year of pertinent clinical laboratory experience in molecular pathology; and
- Be certified by the ASCP, the American Association of Bioanalysts (AAB), the American Board of Histocompatibility and Immunogenetics, or the American Medical Technologists.

Andrology and Embryology Specialists

Andrology and embryology specialists must:[18]

- Have a bachelor's degree with 24 semester hours of academic science, six semester hours of academic biological science, and six semester hours of academic chemical science; and
- Complete training as required by the AAB; and
- Be certified by the AAB; and
- Pass the AAB examination.

Or:

- Have an associate degree with six semester hours of academic biological science and six semester hours of academic chemical science; and
- Complete training as required by the AAB; and
- Be certified by the AAB; and
- Pass the AAB examination.

Histology Specialist

A histology specialist must:[19]

- Have an associate degree; and

[15] Rule 64B3-5.003(3)(c), F.A.C.
[16] Rule 64B3-5.003(3)(d), F.A.C.
[17] Rule 64B3-5.003(3)(e), F.A.C.
[18] Rule 64B3-5.003(3)(f), F.A.C.
[19] Rule 64B3-5.003(3)(g), F.A.C.

- Complete a histotechnology training program approved by the NAACLS; and
- Be certified by the ASCP.

Or:

- Meet education standards as required by the ASCP; and
- Complete training as required by the ASCP; and
- Be certified by the ASCP.

Or:

- Have 60 semester hours with 12 hours of chemical or biological science; and
- Complete a board approved training program; and
- Be certified by the ASCP.

Or:

- Meet education standards as required by the ASCP; and
- Have three years of pertinent experience as a Florida licensed histology technician or equivalent; and
- Be certified by the ASCP.

Or:

- Meet education standards a required by the ASCP; and
- Have five years of pertinent experience and 48 contact hours of continuing education in immunohistochemistry or advanced histologic techniques; and
- Be certified by the ASCP.

Or:

- Meet education standards as required by the ASCP; and
- Have five years of pertinent experience, 48 contact hours of continuing education in immunohistochemistry or advanced histologic techniques, and be a Florida licensed technician in the specialty of histology.

Histocompatibility Specialist

A histocompatibility specialist must be certified by the American Board of Histocompatibility and Immunogenetics (ABHI). To become certified, they must meet the education and training/experience standards of the ABHI.[20]

Technicians

Clinical laboratory technicians are similar to technologists but they are not authorized to interpret clinical laboratory test results and may only perform moderate complexity tests, unless they meet the minimum qualifications for high complexity testing. Such a technician may perform high complexity testing only when under the direct supervision of a licensed technologist or the supervisor or director of the clinical laboratory.[21]

The specialist categories of technician licensure include: generalist technician (which includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and

[20] Rule 64B3-5.003(3)(h), F.A.C.
[21] Rule 64B3-13.004, F.A.C.

immunohematology); histology specialist; andrology and embryology specialists; and molecular pathology specialist.

All applicants for licensure as a technician must satisfy the CLIA requirements for Moderate Complexity Testing, which require the applicant to:[22]

- Be a licensed doctor of medicine, osteopathy, or podiatric medicine; or
- Have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;
- Have earned an associate degree in a chemical, physical, or biological science or medical laboratory technology from an accredited institution; or
- Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks, and have held the military enlisted occupational specialty of medical laboratory specialist; or
- Be a high school graduate or equivalent; and
    - Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.[23]

In addition, Florida law requires an applicant for licensure as a technician to comply with additional education and training requirements for each specialty category of technician licensure.[24]

Generalist Technician Licensure

Licensure as a generalist technician includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and immunohematology. The education, training, and certification requirements for licensure as a generalist technician include the following:[25]

- Have a bachelor's degree; and
- Have three years of pertinent clinical laboratory experience within the ten years immediately preceding application for licensure; and
- Be certified by the ASCP, the American Medical Technologists (AMT), or the AAB.

Or:

- Have an associate degree; and
- Have four years of pertinent clinical laboratory experience within the ten years immediately preceding application for licensure; and
- Be certified by the ASCP, the AMT, or the AAB.

Or:

- Meet education standards as required by the ASCP, the AMT or the AAB; and
- Complete an approved clinical/medical laboratory training program or have five years of pertinent clinical laboratory experience within the ten years immediately preceding application for licensure; and
- Be certified by the ASCP, the AMT, or the AAB.

[22] Rule 64B3-5.004(2), F.A.C., and 42 C.F.R. § 493.1423.
[23] 42 C.F.R. § 493.1423. Such training must ensure that the individual has: the skills required for proper specimen collection, including patient preparation and labeling, handling, preservation, preparation, transportation, and storage of specimens; the skills required for implementing all standard laboratory procedures; the skills required for performing each test method and for proper instrument use; the sills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; the skills required to implement the quality control policies and procedures of the laboratory; the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results; a working knowledge of reagent stability and storage; and an awareness of the factors that influence test results.
[24] Rule 64B3-5.004(3), F.A.C.
[25] Rule 64B3-5.004(3)(a), F.A.C.

Histology Specialist

A histology specialist must be certified by the ASCP. To become certified, they must meet the education and training/experience standards of the ASCP.[26]

Andrology and Embryology Specialists

Andrology and embryology specialists must:[27]

- Have a bachelor's degree; and
- Have six months of pertinent clinical laboratory experience; and
- Be certified by the AAB.

Or:

- Have an associate degree; and
- Have five years of pertinent clinical laboratory experience; and
- Be certified by the AAB.

Or:

- Meet education standards as required by the AAB;
- Complete an approved clinical/medical laboratory training program; and
- Be certified by the AAB.

Molecular Pathology Specialist

Molecular pathology specialists must:[28]

- Have a high school diploma; and
- Be a licensed clinical laboratory technologist or technician in any specialty area; and
- Pass the molecular diagnostics examination; and
- Be certified by the AAB.

[26] Rule 64B3-5.004(3)(b), F.A.C.
[27] Rule 64B3-5.004(3)(c), F.A.C.
[28] Rule 64B3-5.004(3)(d), F.A.C.

Effect of the Bill

The bill requires applicants for licensure to perform high or moderate complexity testing as a clinical laboratory technician or technologist to comply only with the federal CLIA education and training requirements. As a result, such applicants will not be required to also comply with the education and training requirements for specialty categories of technician and technologist licensure.

The bill repeals s. 483.811, which authorizes the Board of Clinical Laboratory Personnel to approve clinical laboratory personnel training programs. Training programs will be approved by accrediting organizations authorized under the CLIA. To conform with this change, the bill also removes authority for DOH to conduct exams, register trainers, and approve curriculum in schools and colleges, and removes authority for DOH to collect fees for exams and training programs

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 483.809, F.S., relating to licensure; examinations; registration of trainees; approval of curricula.
Section 2: Repeals s. 483.811, F.S., relating to approval of laboratory personnel training programs.
Section 3: Amends s. 483.823, F.S., relating to qualifications of clinical laboratory personnel.
Section 4: Amends s. 483.800, F.S., relating to declaration of policy and statement of purpose.
Section 5: Amends s. 483.803, F.S., relating to definitions.
Section 6: Amends s. 483.807, F.S., relating to fees; establishment; disposition.
Section 7: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See fiscal comments.

2. Expenditures:

   See fiscal comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill has no fiscal impact on DOH. The reduction in revenue from the non-collection of fees for exams and training programs will be offset by a reduction in workload for DOH because they will no longer be required to conduct exams, register trainers, or approve curricula.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill does not necessitate rule-making.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to clinical laboratory personnel; amending s. 483.809, F.S.; deleting requirements that the Department of Health conduct examinations for clinical laboratory personnel licensure and register clinical laboratory trainees; deleting the requirement that the Board of Clinical Laboratory Personnel approve training curricula for licensure of clinical laboratory personnel; repealing s. 483.811, F.S., relating to approval of laboratory personnel training programs; amending s. 483.823, F.S.; requiring that applicants for licensure as a technologist or technician who meet specified criteria be deemed to have satisfied minimum qualifications for licensure, as applicable; amending ss. 483.800, 483.803, and 483.807, F.S.; conforming provisions to changes made by the act; making technical changes; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 483.809, Florida Statutes, is amended to read:

483.809 Licensure~~; examinations; registration of trainees; approval of curricula~~.—

~~(1) LICENSING.—~~The department shall provide biennial licensure of all clinical laboratory personnel who the board certifies have met the requirements of this part. The license of any person who fails to pay a required fee or otherwise fails to qualify within 60 days after the date of expiration of such license shall be automatically canceled without notice or further proceedings unless the individual has made application for inactive status pursuant to s. 483.819.

~~(2) EXAMINATIONS.—The department shall conduct examinations required by board rules to determine in part the qualification of clinical laboratory personnel for licensure. The board by rule may designate a national certification examination that may be accepted in lieu of state examination for clinical laboratory personnel or public health scientists.~~

~~(3) REGISTRATION OF TRAINEES.—The department shall provide for registration of clinical laboratory trainees who are enrolled in a training program approved pursuant to s. 483.811, which registration may not be renewed except upon special authorization of the board.~~

~~(4) APPROVAL OF CURRICULUM IN SCHOOLS AND COLLEGES.—The board may approve the curriculum in schools and colleges offering education and training leading toward qualification for licensure under this part.~~

Section 2. Section 483.811, Florida Statutes, is repealed.

Section 3. Subsections (3) and (4) are added to section

483.823, Florida Statutes, to read:

483.823 Qualifications of clinical laboratory personnel.—

(3) Except as otherwise provided in s. 483.812, a technologist or technician applicant for licensure who satisfies the requirements in 42 C.F.R. s. 493.1489 to perform high complexity testing is deemed to have satisfied the minimum qualifications for licensure under this part to perform high complexity testing as a technologist or technician in this state.

(4) Except as otherwise provided in s. 483.812, a technician applicant for licensure who satisfies the requirements in 42 C.F.R. s. 493.1423 to perform moderate complexity testing is deemed to have satisfied the minimum qualifications for licensure under this part to perform moderate complexity testing as a technician in this state.

Section 4. Section 483.800, Florida Statutes, is amended to read:

483.800 Declaration of policy and statement of purpose.—The purpose of this part is to protect the public health, safety, and welfare of the people of this state from the hazards of improper performance by clinical laboratory personnel. Clinical laboratories provide essential services to practitioners of the healing arts by furnishing vital information that is essential to a determination of the nature, cause, and extent of the condition involved. Unreliable and

inaccurate reports may cause unnecessary anxiety, suffering, and financial burdens and may even contribute directly to death. The protection of public and individual health requires the licensure of clinical laboratory personnel who meet minimum requirements for safe practice. ~~The Legislature finds that laboratory testing technology continues to advance rapidly. The Legislature also finds that a hospital training program under the direction of the hospital clinical laboratory director offers an opportunity for individuals already trained in health care professions to expand the scope of their careers. The Legislature further finds that there is an immediate need for properly trained personnel to ensure patient access to testing. Therefore, the Legislature recognizes the patient-focused benefits of hospital-based training for laboratory and nonlaboratory personnel for testing within hospitals and commercial laboratories and recognizes the benefits of a training program approved by the Board of Clinical Laboratory Personnel under the direction of the hospital clinical laboratory director.~~

Section 5. Subsection (5) of section 483.803, Florida Statutes, is amended to read:

483.803 Definitions.—As used in this part, the term:

(5) "Clinical laboratory trainee" means any person having qualifying education who is enrolled in a clinical laboratory training program ~~approved pursuant to s. 483.811~~ and ~~who~~ is

seeking experience required to meet minimum qualifications for licensing in this state. Trainees may perform procedures under direct and responsible supervision of duly licensed clinical laboratory personnel, but they may not report test results.

Section 6. Subsections (1), (3), (8), and (9) of section 483.807, Florida Statutes, are amended to read:

483.807 Fees; establishment; disposition.—

(1) The board shall establish~~,~~ by rule~~, shall establish~~ fees to be paid for application, ~~examination, reexamination,~~ licensing and renewal, ~~registration, laboratory training program application,~~ reinstatement, and recordmaking and recordkeeping. The board may also establish~~,~~ by rule~~,~~ a delinquency fee. The board shall establish fees that are adequate to ensure the continued operation of the board and to fund the proportionate expenses incurred by the department in carrying out its licensure and other related responsibilities under this part. Fees must ~~shall~~ be based on departmental estimates of the revenue required to implement this part and the provisions of law with respect to the regulation of clinical laboratory personnel.

~~(3) The examination fee shall be in an amount which covers the costs of obtaining and administering the examination and shall be refunded if the applicant is found ineligible to sit for the examination. The combined fees for initial application and examination may not exceed $200 plus the actual per~~

~~applicant cost to the department for developing, administering, or procuring the licensure examination.~~

~~(8) The initial application fee for registration of a trainee shall not exceed $20.~~

~~(9) The initial application and renewal fee for approval as a laboratory training program may not exceed $300. The fee for late filing of a renewal application shall be $50.~~

Section 7. This act shall take effect July 1, 2024.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1405 Acupuncture
SPONSOR(S): Altman
TIED BILLS: **IDEN./SIM. BILLS:** SB 614

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Acupuncture is a form of health care based on traditional Chinese medical concepts and modern “oriental” techniques for the purpose of the promotion, maintenance, and restoration of health and the prevention of disease. Acupuncture involves the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body and the use of electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies.

The Board of Acupuncture (Board) within the Department of Health (DOH) is responsible for the licensure and regulation of acupuncturists in the state. There are 2,672 acupuncturists currently licensed to practice in Florida.

HB 1405 significantly revises the acupuncture practice act which regulates the practice and licensure of acupuncture in Florida. The bill updates terminology throughout the practice act to use contemporary terminology, creates “acupuncture assistant” as an unlicensed profession, and creates a scope of practice for acupuncturists.

The bill revises the educational requirements for a person seeking initial licensure as an acupuncturist. The bill adds practice management to the list of subjects which may be included in continuing education courses.

The bill exempts a person acting in the capacity or guest instructor or guest practitioner from the prohibition on the unlicensed practice of acupuncture.

The bill has an indeterminant negative fiscal impact on state government, and no impact on local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Licensure and Regulation of Acupuncture

Acupuncture is a form of health care based on traditional Chinese medical concepts and modern "oriental" techniques for the purpose of the promotion, maintenance, and restoration of health and the prevention of disease. Acupuncture involves the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body and the use of electroacupuncture, Qi Gong,[1] oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies.[2]

There are 2,672 acupuncturists currently licensed to practice in Florida.[3]

Board of Acupuncture

The Board of Acupuncture (Board) within the Department of Health (DOH) is responsible for the licensure and regulation of acupuncturists. The Board consists of seven members appointed by the Governor and confirmed by the Florida Senate. The board must include five licensed acupuncturists and two laypersons who have never been acupuncturists or members of a closely related profession.[4]

Licensure Requirements

To be licensed to practice acupuncture, a person must apply to DOH and meet all of the following criteria:[5]

- Be at least 21 years of age, have good moral character, and the ability to communicate in English;
- Have completed 60 college credits from an accredited post-secondary institution;
- Have completed a four-year course of study in acupuncture and oriental medicine which meets the standards set by the Board and includes, at a minimum, courses in western anatomy, physiology, pathology, and biomedical terminology, first aid, and cardiopulmonary resuscitation (CPR);[6] and
- Pay the required fees set by the Board.

In addition to meeting all of the criteria listed above, an applicant must also meet one of the following requirements:[7]

- Has successfully completed a board-approved national certification;
- Is actively licensed to practice in a state with examination requirements that are substantially equivalent to, or more stringent than, Florida's requirements; or
- Passes an examination administered by DOH.[8]

[1] Qi Gong is the Chinese system of energy cultivation which uses posture, movement, exercises, breathing, meditation, visualization, and conscious intent to move, cleanse, or purify Qi (vital energy) to promote, maintain and restore health and to prevent disease. *See*, Rule 64B1-4.006, F.A.C.
[2] S. 457.102(1), F.S.
[3] Department of Health, *License Verification Look-up*. Available at https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited January 29, 2024).
[4] S. 457.103, F.S.
[5] S. 457.105, F.S.
[6] Individuals who were enrolled in a course of study prior to August 1, 1997 were eligible for licensure upon completion of a two-year course of study which adhered to Board-established standards. *See*, s. 457.105(2)(b), F.S.
[7] S. 457.105, F.S.

Acupuncturists are required to renew their license to practice biennially. As a condition of licensure renewal, a licensed acupuncturist is required to complete a minimum of 30 hours of continuing education per biennium.[9] Continuing education programs must be in acupuncture or oriental medicine subjects, including, but not limited to, anatomy, biological sciences, adjunctive therapies, sanitation and sterilization, emergency protocols, and diseases.[10] The Board is responsible for evaluating and approving all continuing education courses.[11]

Scope of Practice

Current law does not expressly outline a scope of practice for acupuncturists. Acupuncturists are licensed to practice acupuncture, which is defined in s. 457.102, F.S., as a form of primary health care, based on traditional Chinese medical concepts and modern oriental medical techniques, that employs acupuncture diagnosis and treatment, as well as adjunctive therapies and diagnostic techniques, for the promotion, maintenance, and restoration of health and the prevention of disease.

Acupuncture includes, but is not limited to, the insertion of acupuncture needles and the application of moxibustion[12] to specific areas of the human body and the use of electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies. Current law allows the Board discretion in defining these terms.[13]

Current law describes an acupuncturist's prescriptive authority which authorizes an acupuncturist to prescribe, administer, and use needles and other devices used in the practice of acupuncture and oriental medicine.[14]

Prohibited Acts

Current law prohibits the following in regard to the licensed practice of acupuncture:[15]

- The practice acupuncture unless the person is licensed under the acupuncture practice act;
- The use, in connection with his or her name or place of business, any title or description of services which incorporates the words "acupuncture," "acupuncturist," "certified acupuncturist," "licensed acupuncturist," "oriental medical practitioner"; the letters "L.Ac.," "R.Ac.," "A.P.," or "D.O.M."; or any other words, letters, abbreviations, or insignia indicating or implying the practice of acupuncture, unless the person is licensed under the acupuncture practice act;
- Presenting as his or her own the license of another;
- Knowingly giving false or forged evidence to the board or a member thereof;
- The use or attempted use of a license that has been suspended, revoked, or placed on inactive or delinquent status;
- The employ of any person who is not licensed pursuant to the acupuncture practice act to engage in the practice of acupuncture; or
- The concealing of information relating to any violation of the acupuncture practice act.

A person who violates this section commits a misdemeanor of the second degree, punishable as provided in ss. 775.082 and 775.083, F.S.[16]

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[8] The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) examination consisting of the Foundations of Oriental Medicine Module, the Acupuncture with Point Location Module, the Biomedicine Module and the Chinese Herbology Module is the Board-approved licensure examination. *See*, 64B1-3.004, F.A.C.
[9] S. 457.107, F.S., and Rule 64B1-7.0015, F.A.C.
[10] S. 457.107, F.S.
[11] Rule 64B1-6.005, F.A.C.
[12] Moxibustion is an external treatment based in traditional Chinese medicine. The practice involves the burning moxa, an herb, adjacent to specific acupuncture points. *See*, Deng, H., & Shen, X. *The mechanism of moxibustion: ancient theory and modern research*. (2013). Evidence-based complementary and alternative medicine https://doi.org/10.1155/2013/379291
[13] S. 457.102(1), F.S.; *see also*, 64B1-3.001, F.A.C.
[14] S. 457.102(7), F.S.
[15] S. 457.116, F.S.

Effect of the Bill

HB 1405 significantly revises the acupuncture practice act which regulates the practice and licensure of acupuncture in Florida.

HB 1405 revises the definition of acupuncture to align with modern nomenclature used to describe the practice. The bill deletes references to "Chinese," and "oriental," medicine and replaces them with "Eastern" medicine. The bill defines "Eastern medicine" as a primary health care system of medicine that includes differential diagnoses and treatment principles, modalities, procedures, and techniques employing acupuncture; traditional and contemporary Eastern medicine; herbal medicine; adjunctive therapies; biological sciences; and medical assessments, examinations, and evaluations for the promotion, maintenance, and restoration of health and the prevention of human disease. The bill makes conforming changes throughout the acupuncture practice act.

The bill creates "acupuncture assistant" as an unlicensed profession. An acupuncture assistant is an unlicensed person who has completed an accredited certification program approved by the Board for the purpose of assisting a licensed acupuncturist. An acupuncture assistant may check on patients and remove acupuncture needles, but may not alter an acupuncture plan of care or insert acupuncture needles. The bill authorizes the Board to specify additional activities and duties appropriate for an acupuncture assistant through rule.

Licensure Requirements

HB 1405 revises the educational requirements for licensure as an acupuncturist. Effective July 1, 2026, the bill requires an individual complete a minimum of 90 college credits leading to a bachelor's degree from a college or university which is accredited by an accrediting agency recognized and approved by the US Department of Education, or a foreign college, university, or institution program.

The bill specifies that the required four-year course of study in acupuncture must be from an accredited program, and effective July 30, 2030, such course of study must terminate with the completion of a doctoral degree in acupuncture that is recognized and approved by the US Department of Education.[17]

The bill revises the licensure pathways for individuals who have completed a board-approved national certification or have been licensed to practice acupuncture in another US state.

The bill adds "practice management" to the list of subjects which may be included in Board-approved continuing education courses. The bill defines "practice management" as the development or mechanics of establishing and managing an office, including enhancement of patient care, risk management, cybersecurity, cost containment, health care documentation, and insurance coding, billing, and claims processing. The bill specifies that up to six hours of practice management continuing education courses may be applied toward a licensee's biennial continuing education requirement.

The bill expressly states that a person licensed to practice acupuncture may not advertise or practice as a physician, an osteopathic physician, or a chiropractic physician, unless he or she maintains an active license to practice in such profession.

Scope of Practice

HB 1405 creates a new section of statute outlining the scope of practice for acupuncturists and acupuncture assistants.

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[16] S. 457.116(2), F.S.; The punishment for such a misdemeanor consists of up to 60 days of imprisonment and a fine up to $500; *see*, ss. 775.082 and 775.083, F.S.

[17] The US Department of Education does not directly approve and recognize specific educational programs. Rather, the US Department of Education recognizes accrediting agencies that evaluate and accredit specific programs. See, US Department of Education, *Accreditation in the United States*. Available at https://www2.ed.gov/admins/finaid/accred/accreditation.html#Overview (last visited January 30, 2024).

Under the bill, the scope of practice for an acupuncturist includes, but is not limited to, the following:

- Examination, evaluation, analysis, diagnosis, management, and treatment services;
- The use and ordering of testing procedures, diagnostic imaging, and laboratory tests; and
- The stimulation of points, areas of the body, and tissues within the body using acupuncture and Eastern medicine, herbal medicine therapies, nutritional substances, point injection, sterile solutions, qi, medical instruments, and other devices or means, as defined by Board rule.

The bill directs the Board to periodically revise the use of acupuncture point injection therapies in rule based on national standards of practice.

The bill expands an acupuncturist's prescriptive authority to include medical devices, the use of diagnostic laboratory tests and imaging procedures, and acupuncture point injection therapies which include the injection of botanical and herbal medicines, nutritional substances, or sterile solutions that are used in the practice of acupuncture and Eastern medicine.

Prohibited Acts

The bill exempts a person acting in the capacity or guest instructor or guest practitioner from the prohibition on the unlicensed practice of acupuncture. The bill directs the Board to establish rules to implement this provision, including exemption for teaching approved courses and practicing acupuncture in response to a declared disaster or emergency.

The bill also establishes title protection, adding "acupuncture physician" to the list of titles which may not be used by a person who is not licensed to practice acupuncture to describe oneself or place of business.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 457.102, F.S., relating to definitions.
Section 2: Amends s. 457.105, F.S., relating to licensure qualifications and fees.
Section 3: Creates s. 457.106, F.S., relating to scope of practice for acupuncturists and acupuncture assistants.
Section 4: Amends s. 457.107, F.S., relating to renewal of licenses; continuing education.
Section 5: Amends s. 457.116, F.S., relating to prohibited acts; penalty.
Section 6: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Sufficient rule-making authority exists to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill currently requires that the course of study in acupuncture be recognized and approved by the US Department of Education, however, the US Department of Education does not recognize individual course of study, and instead recognizes accrediting agencies which evaluate and accredit individual programs.[18]

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

[18] *See*, US Department of Education, *Accreditation in the United States*. Available at https://www2.ed.gov/admins/finaid/accred/accreditation.html#Overview (last visited January 30, 2024).

A bill to be entitled

An act relating to acupuncture; amending s. 457.102, F.S.; revising and providing definitions; amending s. 457.105, F.S.; revising criteria for a person to become licensed to practice acupuncture; prohibiting certain persons from advertising or practicing as a physician, an osteopathic physician, or a chiropractic physician; providing an exception; creating s. 457.106, F.S.; providing for the scope of practice for an acupuncturist and an acupuncture assistant; requiring the Board of Acupuncture to revise the use of specified therapies based on national standards of practice; amending s. 457.107, F.S.; requiring education programs for licensure renewals to be approved by the Board of Acupuncture; revising continuing professional education requirements; providing a definition; amending s. 457.116, F.S.; authorizing a person to practice acupuncture and use specified titles without a license under specified circumstances; requiring the board to establish by rule certain requirements for such unlicensed practice; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 457.102, Florida Statutes, is amended to read:

457.102 Definitions.—As used in this chapter:

(1) "Acupuncture" means a skilled intervention and form of primary health care, based on traditional and contemporary Eastern medicine and biological sciences ~~Chinese medical concepts and modern oriental medical techniques~~, that employs acupuncture diagnosis and treatment, as well as adjunctive therapies and diagnostic techniques, for the promotion, maintenance, and restoration of health and the prevention of disease. Acupuncture shall include, but not be limited to, the insertion, stimulation, and removal of acupuncture needles and the application of moxibustion to specific areas of the human body and the use of electroacupuncture, Qi Gong, Eastern ~~oriental~~ massage and bodywork, herbal therapy, dietary guidelines, and other adjunctive therapies, as defined by board rule.

(2) "Acupuncture assistant" means an unlicensed person who has completed an accredited certification program approved by the board for the purpose of assisting a licensee under this chapter.

(3) ~~(2)~~ "Acupuncturist" means a practitioner of Eastern medicine who is ~~any person~~ licensed under ~~as provided in~~ this chapter to practice acupuncture as a primary health care provider.

(4) ~~(3)~~ "Board" means the Board of Acupuncture.

(5) "Department" means the Department of Health.

(6) "Direct supervision" means the immediate supervision by a licensed acupuncturist, with the licensee assuming legal liability for the supervised actions. The board shall establish by rule what constitutes direct supervision under this chapter.

(7) ~~(6)~~ "Eastern ~~Oriental~~ medicine" means the use of a primary health care system of medicine that includes differential diagnoses and treatment principles, modalities, procedures, and techniques employing acupuncture; traditional and contemporary Eastern medicine; herbal medicine; adjunctive therapies; biological sciences; and medical assessments, examinations, and evaluations for the promotion, maintenance, and restoration of health and the prevention of human disease ~~acupuncture, electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies~~.

(8) ~~(4)~~ "License" means the document of authorization issued by the department for a person to engage in the practice of acupuncture.

(9) ~~(7)~~ "Prescriptive rights" means the prescription, administration, and use of needles, medical ~~and~~ devices, restricted devices, and prescription devices; diagnostic laboratory tests and imaging procedures; and acupuncture point injection therapies which include the injection of botanical and

herbal medicines, nutritional substances, or sterile solutions that are used in the practice of acupuncture and Eastern ~~oriental~~ medicine.

Section 2. Subsection (2) of section 457.105, Florida Statutes, is amended, and subsection (3) is added to that section, to read:

457.105 Licensure qualifications and fees.—

(2) A person may become licensed to practice acupuncture if the person applies to the department and meets all of the following criteria:

(a) Is 21 years of age or older, has good moral character, and has the ability to communicate in English, which is demonstrated by having passed the national written examination in English or, if such examination was passed in a foreign language, by also having passed a nationally recognized English proficiency examination.~~;~~

(b) Has completed 60 college credits from an accredited postsecondary institution and, effective July 1, 2026, has completed a minimum of 90 college credits leading to a bachelor's degree from a liberal arts college or a university accredited by an accrediting agency recognized and approved by the United States Department of Education, or a foreign college, university, or institution program, as a prerequisite to enrollment in an authorized, accredited ~~3-year course of study in acupuncture and oriental medicine, and has completed a 3-year~~

~~course of study in acupuncture and oriental medicine, and effective July 31, 2001, a~~ 4-year course of study in acupuncture and Eastern ~~oriental~~ medicine, which, effective July 30, 2030, terminates with the completion of a doctoral degree in acupuncture that is recognized and approved by the United States Department of Education and which meets standards established by the board by rule, including ~~which standards include~~, but ~~are~~ not limited to, successful completion of academic courses in western anatomy, western physiology, western pathology, western biomedical terminology, first aid, and cardiopulmonary resuscitation (CPR). However, any person who enrolled in an authorized course of study in acupuncture before August 1, 1997, must have completed only a 2-year course of study which meets standards established by the board by rule, which standards must include, but are not limited to, successful completion of academic courses in western anatomy, western physiology, and western pathology.~~;~~

(c) Has successfully completed a board-approved national examination and certification process, is actively licensed in a state that has examination and licensing qualification requirements that are substantially equivalent to or more stringent than those required by ~~of~~ this state, or passes an examination administered by the department, which examination tests the applicant's competency and knowledge of the practice of acupuncture and Eastern ~~oriental~~ medicine. At the request of

any applicant, traditional ~~oriental~~ nomenclature for the points shall be used in the examination. The examination shall include a practical examination of the knowledge and skills required to practice modern and traditional acupuncture and Eastern ~~oriental~~ medicine, covering diagnostic and treatment techniques and procedures.~~; and~~

(d) Pays the required fees set by the board by rule not to exceed the following amounts:

1. Examination fee: $500 plus the actual per applicant cost to the department for purchase of the written and practical portions of the examination from a national organization approved by the board.

2. Application fee: $300.

3. Reexamination fee: $500 plus the actual per applicant cost to the department for purchase of the written and practical portions of the examination from a national organization approved by the board.

4. Initial biennial licensure fee: $400, if licensed in the first half of the biennium, and $200, if licensed in the second half of the biennium.

(3) A person licensed under this section may not advertise or practice as a physician, an osteopathic physician, or a chiropractic physician unless he or she maintains an active license to practice as such physician under chapter 458, chapter 459, or chapter 460.

Section 3. Section 457.106, Florida Statutes, is created to read:

457.106 Scope of practice for acupuncturists and acupuncture assistants.—

(1)(a) The scope of practice for an acupuncturist includes those acts, modalities, procedures, techniques, and interventions a licensee is authorized to provide under this chapter in person or remotely using telehealth, including, but not limited to:

1. Examination, evaluation, analysis, diagnosis, management, and treatment services.

2. The use and ordering of testing procedures, diagnostic imaging, and laboratory tests.

3. The stimulation of points, areas of the body, and tissues or substances within the body using acupuncture and Eastern medicine, herbal medicine therapies, nutritional substances, point injection, sterile solutions, qi, medical instruments, and other devices or means, as defined by board rule.

(b) The board shall periodically revise the use of acupuncture point injection therapies as described in rule under 64B1-4.012, Florida Administrative Code, based on national standards of practice.

(2) Activities and duties for an acupuncture assistant shall be defined by board rule and may include, but not be

limited to, checking on patients and removing acupuncture needles. Prohibited activities and duties may include, but not be limited to, developing or altering an acupuncture plan of care and the insertion of acupuncture needles.

Section 4. Subsection (3) of section 457.107, Florida Statutes, is amended to read:

457.107 Renewal of licenses; continuing education.—

(3) The board shall prescribe by rule continuing education requirements of up to 30 hours biennially as a condition for renewal of a license. All education programs must be approved by the board and ~~that~~ contribute to the advancement, extension, or enhancement of professional skills and knowledge related to the practice of acupuncture, whether conducted by a nonprofit or profitmaking entity~~, are eligible for approval~~. The continuing professional education requirements must be in acupuncture or Eastern ~~oriental~~ medicine subjects, including, but not limited to, anatomy, biological sciences, adjunctive therapies, sanitation and sterilization, emergency protocols, ~~and~~ diseases, and practice management. As used in this subsection, the term "practice management" means the development or mechanics of establishing and managing an office, including enhancement of patient care, risk management, cybersecurity, cost containment, health care documentation, and insurance coding, billing, and claims processing. Up to 6 hours of practice management continuing education may be applied to satisfy the requirements

for license renewal per biennium licensing period. The board may set a fee of up to $100 for each continuing education provider. The licensee shall retain in his or her records the certificates of completion of continuing professional education requirements. All national and state acupuncture and Eastern ~~oriental~~ medicine organizations and acupuncture and Eastern ~~oriental~~ medicine schools are approved to provide continuing professional education in accordance with this subsection.

Section 5. Paragraphs (a) and (b) of subsection (1) of section 457.116, Florida Statutes, are amended to read:

457.116 Prohibited acts; penalty.—

(1) A person may not:

(a) Practice acupuncture unless the person is licensed under ss. 457.101-457.118, except if the person is acting in the capacity of a guest instructor or a guest practitioner. The board shall establish by rule a definition, scope of practice, and other conditions necessary to implement a guest instructor and a guest practitioner exemption for teaching approved courses and practicing acupuncture in response to a declared disaster or emergency;

(b) Use, in connection with his or her name or place of business, any title or description of services which incorporates the words "acupuncture," "acupuncturist," "certified acupuncturist," "licensed acupuncturist," or "acupuncture physician" ~~"oriental medical practitioner"~~; the

letters "L.Ac.," "R.Ac.," or "A.P." ~~"A.P.," or "D.O.M."~~; or any other words, letters, abbreviations, or insignia indicating or implying that he or she practices acupuncture unless he or she is a holder of a valid license issued pursuant to ss. 457.101-457.118;

Section 6. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Altman offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 457.102, Florida Statutes, is amended to read:

457.102 Definitions.—As used in this chapter:

(1) "Acupuncture" means a skilled intervention and form of primary health care, based on traditional Chinese medicine, contemporary Eastern medicine and biological sciences ~~medical concepts and modern oriental medical techniques~~, that employs acupuncture diagnosis and treatment, as well as adjunctive therapies and diagnostic techniques, for the promotion, maintenance, and restoration of health and the prevention of

disease. Acupuncture shall include, but not be limited to, the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body and the use of electroacupuncture, Qi Gong, Eastern ~~oriental~~ massage and bodywork, herbal therapy, dietary guidelines, and other adjunctive therapies, as defined by board rule.

(2) "Acupuncturist" means a practitioner of Eastern medicine who is ~~any person~~ licensed under ~~as provided in~~ this chapter to practice acupuncture as a primary health care provider.

(3) "Board" means the Board of Acupuncture.

(4)~~(5)~~ "Department" means the Department of Health.

(6) "Direct supervision" means the immediate supervision by a licensed acupuncturist, with the licensee assuming legal liability for the supervised actions. The board shall establish by rule what constitutes direct supervision under this chapter.

(7) "Doctor of Acupuncture and Chinese Herbal Medicine" means an acupuncturist licensed under this chapter who has completed a doctoral degree in Acupuncture and Chinese Medicine.

(8) "Doctor of Acupuncture and Oriental Medicine" means an acupuncturist licensed under this chapter who has completed a doctoral degree in Acupuncture and Oriental Medicine.

(9)~~(6)~~ "Eastern ~~Oriental~~ medicine" means the use of a primary health care system of medicine that includes differential diagnoses and treatment principles, modalities,

procedures, and techniques employing acupuncture; traditional Chinese medicine; contemporary Eastern medicine; herbal medicine; adjunctive therapies; biological sciences; and medical assessments, examinations, and evaluations for the promotion, maintenance, and restoration of health and the prevention of human disease ~~acupuncture, electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies~~.

(10) ~~(4)~~ "License" means the document of authorization issued by the department for a person to engage in the practice of acupuncture.

(11) ~~(7)~~ "Prescriptive rights" means the prescription, administration, and use of needles, medical ~~and~~ devices, restricted devices, and prescription devices; diagnostic laboratory tests and imaging procedures; botanical and herbal medicines; nutritional substances; and acupuncture point injection therapies which include the injection of sterile solutions that are used in the practice of acupuncture and Eastern ~~oriental~~ medicine.

Section 2. Subsection (2) of section 457.105, Florida Statutes, is amended to read:

457.105 Licensure qualifications and fees.—

(2) A person may become licensed to practice acupuncture if the person applies to the department and meets all of the following criteria:

(a) Is 21 years of age or older, has good moral character, and has the ability to communicate in English, which is demonstrated by having passed the national written examination in English or, if such examination was passed in a foreign language, by also having passed a nationally recognized English proficiency examination.~~;~~

(b) Has completed 60 college credits from an accredited postsecondary institution and, effective July 1, 2032, has completed a minimum of 90 semester credits leading to a bachelor's degree from a liberal arts college or a university accredited by an accrediting agency recognized and approved by the United States Department of Education, or a foreign college, university, or institution program, as a prerequisite to enrollment in an authorized, accredited ~~3-year course of study in acupuncture and oriental medicine, and has completed a 3-year course of study in acupuncture and oriental medicine, and effective July 31, 2001, a~~ 4-year course of study in acupuncture and Eastern ~~oriental~~ medicine, which, effective July 30, 2036, terminates with the completion of a doctoral degree in acupuncture that is recognized and approved by the United States Department of Education and which meets standards established by the board by rule, including ~~which standards include~~, but ~~are~~ not limited to, successful completion of academic courses in western anatomy, western physiology, western pathology, western biomedical terminology, first aid, and cardiopulmonary

resuscitation (CPR). However, any person who enrolled in an authorized course of study in acupuncture before August 1, 1997, must have completed only a 2-year course of study which meets standards established by the board by rule, which standards must include, but are not limited to, successful completion of academic courses in western anatomy, western physiology, and western pathology.~~;~~

(c) Has successfully completed a board-approved national examination and certification process, is actively licensed in a state that has examination and licensing qualification requirements that are substantially equivalent to or more stringent than those required by ~~of~~ this state, or passes an examination administered by the department, which examination tests the applicant's competency and knowledge of the practice of acupuncture and Eastern ~~oriental~~ medicine. At the request of any applicant, traditional ~~oriental~~ nomenclature for the points shall be used in the examination. The examination shall include a practical examination of the knowledge and skills required to practice modern and traditional acupuncture and oriental medicine, covering diagnostic and treatment techniques and procedures.~~; and~~

(d) Pays the required fees set by the board by rule not to exceed the following amounts:

1. Examination fee: $500 plus the actual per applicant cost to the department for purchase of the written and practical

portions of the examination from a national organization approved by the board.

2. Application fee: $300.

3. Reexamination fee: $500 plus the actual per applicant cost to the department for purchase of the written and practical portions of the examination from a national organization approved by the board.

4. Initial biennial licensure fee: $400, if licensed in the first half of the biennium, and $200, if licensed in the second half of the biennium.

Section 3. Section 457.106, Florida Statutes, is created to read:

457.106 Scope of practice for acupuncturists.—

(1) The scope of practice for an acupuncturist includes those acts, modalities, procedures, techniques, and interventions a licensee is authorized to provide under this chapter, including, but not limited to:

(a) Examination, evaluation and management, analysis, diagnosis, and treatment services.

(b) The use and ordering of testing procedures, diagnostic imaging, and laboratory tests.

(c) The stimulation of points, areas of the body, and tissues or substances within the body using acupuncture and Eastern medicine, herbal medicine therapies, nutritional substances, point injection, sterile solutions, qi, medical

instruments, and other devices or means, as defined by board rule.

(2) The board shall periodically revise the use of acupuncture point injection therapies based on national standards of practice.

Section 4. Subsection (3) of section 457.107, Florida Statutes, is amended to read:

457.107 Renewal of licenses; continuing education.—

(3) The board shall prescribe by rule continuing education requirements of up to 30 hours biennially as a condition for renewal of a license. All education programs must be approved by the board and ~~that~~ contribute to the advancement, extension, or enhancement of professional skills and knowledge related to the practice of acupuncture, whether conducted by a nonprofit or profitmaking entity~~, are eligible for approval~~. The continuing professional education requirements must be in acupuncture or Eastern ~~oriental~~ medicine subjects, including, but not limited to, anatomy, biological sciences, adjunctive therapies, sanitation and sterilization, emergency protocols, ~~and~~ diseases, and practice management. As used in this subsection, the term "practice management" means the development or mechanics of establishing and managing an office, including enhancement of patient care, risk management, cybersecurity, cost containment, health care documentation, and insurance coding, billing, and claims processing. Up to 6 hours of practice management

continuing education may be applied to satisfy the requirements for license renewal per biennium licensing period. The board may set a fee of up to $100 for each continuing education provider. The licensee shall retain in his or her records the certificates of completion of continuing professional education requirements. All national and state acupuncture and Eastern ~~oriental~~ medicine organizations and acupuncture and Eastern ~~oriental~~ medicine schools are approved to provide continuing professional education in accordance with this subsection.

Section 5. Paragraph (a) of subsection (1) of section 457.116, Florida Statutes, is amended to read:

457.116 Prohibited acts; penalty.—

(1) A person may not:

(a) Practice acupuncture unless the person is licensed under ss. 457.101-457.118, unless the person is practicing in the capacity of a guest instructor or in response to a declared disaster or emergency, if the person holds an active license to practice acupuncture in another state, the District of Columbia, or a possession or territory of the United States and maintains medical malpractice insurance or proof of financial responsibility that meets the minimum requirements for licensure as set by the board. The board shall establish by rule a definition, scope of practice, and other conditions necessary to implement a guest instructor and a guest practitioner exemption

for teaching approved courses and practicing acupuncture in response to a declared disaster or emergency;

Section 6. This act shall take effect July 1, 2024.

T I T L E A M E N D M E N T

Remove lines 10-19 and insert:

an acupuncturist; requiring the Board of Acupuncture to revise the use of specified therapies based on national standards of practice; amending s. 457.107, F.S.; requiring education programs for licensure renewals to be approved by the Board of Acupuncture; revising continuing professional education requirements; providing a definition; amending s. 457.116, F.S.; authorizing a person to practice acupuncture without a license under specified

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1435 Medical Marijuana Use Registry Identification Cards for Veterans
SPONSOR(S): Valdés
TIED BILLS: **IDEN./SIM. BILLS:** SB 1514

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		McElroy	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Section 381.986, F.S., authorizes patients with certain debilitating medical conditions to obtain medical marijuana from Medical Marijuana Treatment Centers (MMTC). To certify a patient for medical use of marijuana, a qualified physician must conduct a physical examination of the patient and determine that the patient has a qualifying medical condition and that medical marijuana would likely outweigh the health risks to the patient. After diagnosing a patient with a qualifying condition, a qualified physician must review and enter certain data into the medical marijuana use registry.

A qualified patient must have a physician certification in the medical marijuana use registry and have a valid medical marijuana use registry identification card to obtain medical marijuana and medical marijuana delivery devices from a MMTC. The Department of Health (DOH), through the Office of Medical Marijuana Use (OMMU), must issue medical marijuana use registry identification cards to qualified patients and caregivers who are residents of this state. The identification cards must be resistant to counterfeiting and tampering and must include, at a minimum, the following:

- The name, address, and date of birth of the qualified patient or caregiver;
- A full-face, passport-type, color photograph of the qualified patient or caregiver taken within the 90 days immediately preceding registration or the Florida driver license or Florida identification card photograph of the qualified patient or caregiver obtained directly from the Department of Highway Safety and Motor Vehicles;
- Identification as a qualified patient or a caregiver;
- The unique numeric identifier used for the qualified patient in the medical marijuana use registry; and
- The expiration date of the identification card.

As of January 26, 2024, there are 871,459 qualified patients with active medical marijuana use registry identification cards. The OMMU processes applications for identification cards within 5 business days of receipt of a complete application. The annual application fee is $75 and OMMU does not currently offer a reduction or waiver of this fee.

Florida is home to 21 military installations and 69,290 military personnel. Florida also has the nation's third-largest veteran population with almost 1.4 million veterans.

HB 1435 exempts individuals who can prove their status as veterans from the annual medical marijuana use registry identification card fee.

The bill has an indeterminate, negative fiscal impact on DOH and no fiscal impact local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Marijuana for Medical Use

Section 381.986, F.S., authorizes patients with any of the following debilitating medical conditions to obtain medical marijuana from Medical Marijuana Treatment Centers (MMTC):

- Cancer
- Epilepsy
- Glaucoma
- Positive status for human immunodeficiency virus
- Acquired immune deficiency syndrome
- Post-traumatic stress disorder
- Amyotrophic lateral sclerosis
- Crohn's disease
- Parkinson's disease
- Multiple sclerosis
- Medical conditions of the same kind or class as or comparable to those enumerated above

To obtain marijuana for medical use from a MMTC, and maintain the immunity from criminal prosecution, the patient must obtain a physician certification from a qualified physician[1] and an identification card from DOH.

Physician Certification

To certify a patient for medical use of marijuana, a qualified physician must conduct a physical examination of the patient and determine that the patient has a qualifying medical condition and that medical marijuana would likely outweigh the health risks to the patient.[2] A qualified physician must be physically present in the same room when conducting the initial examination on a qualified patient.[3] The physician must evaluate an existing patient at least once every 30 weeks before issuing a renewal physician certification.[4] Under current law, the physician must conduct the in-person[5] physical examination of the patient to issue the initial certification and may conduct any subsequent examinations for renewal certifications through telehealth.[6]

After diagnosing a patient with a qualifying condition, a qualified physician must review and enter certain data into the medical marijuana use registry. The physician must review the medical marijuana use registry and confirm that the patient does not have an active physician certification from another qualified physician.[7] The physician must then register as the issuer of the physician certification for the named qualified patient in the medical marijuana use registry and enter into the registry the contents of the physician certification, including the patient's qualifying condition, the dosage, the amount and forms of marijuana authorized, and any types of marijuana delivery devices needed by the patient.[8]

Medical Marijuana Use Registry Identification Card

[1] To certify patients for medical use of marijuana, a physician must hold an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and comply with certain physician education requirements. See ss. 381.986(1)(m), F.S. and 381.986(3)(a), F.S.
[2] S. 381.986, F.S.
[3] S. 381.986(a), F.S.
[4] S. 381.986(4)(g), F.S.
[5] This means that the physician must be physically present and in the same room as the patient. S. 381.986(4)(a)1, F.S.
[6] S. 381.986, F.S.
[7] *Id.*
[8] *Id.*

A qualified patient must have a physician certification in the medical marijuana use registry and have a valid medical marijuana use registry identification card to obtain medical marijuana and medical marijuana delivery devices from a MMTC. The Department of Health (DOH) must issue medical marijuana use registry identification cards to qualified patients and caregivers who are residents of this state. The identification cards must be resistant to counterfeiting and tampering and must include, at a minimum, the following:

- The name, address, and date of birth of the qualified patient or caregiver;
- A full-face, passport-type, color photograph of the qualified patient or caregiver taken within the 90 days immediately preceding registration or the Florida driver license or Florida identification card photograph of the qualified patient or caregiver obtained directly from the Department of Highway Safety and Motor Vehicles;
- Identification as a qualified patient or a caregiver;
- The unique numeric identifier used for the qualified patient in the medical marijuana use registry;
- For a caregiver, the name and unique numeric identifier of the caregiver and the qualified patient or patients that the caregiver is assisting; and
- The expiration date of the identification card.

As of January 26, 2024, there are 871,459 qualified patients with active medical marijuana use registry identification cards.[9] The Office of Medical Marijuana Use (OMMU) processes applications for identification cards within 5 business days of receipt of a complete application. The annual application fee is $75 and OMMU does not currently offer a reduction or waiver of this fee.

Veterans

Florida is home to 21 military installations[10] and 69,290 military personnel.[11] Florida also has the nation's third-largest veteran[12] population with almost 1.4 million veterans.[13] Many of these veterans are recently transitioned servicemembers.

The U.S. Department of Veterans Affairs has issued informational guidance for the use of medical marijuana by veterans:[14]

- Veterans will not be denied VA benefits because of marijuana use.
- Veterans are encouraged to discuss marijuana use with their VA providers.
- VA health care providers will record marijuana use in the Veteran's VA medical record in order to have the information available in treatment planning. As with all clinical information, this is part of the confidential medical record and protected under patient privacy and confidentiality laws and regulations.
- VA clinicians may not recommend medical marijuana.

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[9] *Office of Medical Marijuana Use Weekly Updates, January 26, 2024,* DOH, Office of Medical Marijuana Use, available at https://knowthefactsmmj.com/wp-content/uploads/ommu_updates/2024/012624-OMMU-Update.pdf (last visited on January 29, 2024).

[10] Select Florida, *Defense & Homeland Security,* 2, https://selectflorida.org/wp-content/uploads/defense-and-homeland-security-industry-profile.pdf (last visited Jan. 26, 2024).

[11] Data from September 2021. Florida Military & Defense, *Economic Impact Summary* (2022), 2, available at https://selectflorida.org/wp-content/uploads/Florida-2022-EIS-Summary-Book-Final.pdf (last visited Jan. 26, 2024).

[12] S. 1.01(14), F.S., defines a "veteran" as a person who served in the active military, naval, or air service and who was discharged or released under honorable conditions, or who later received an upgraded discharge under honorable conditions. The definition in s. 1.01(14), F.S., is cited in numerous statutes, including ss. 117.02, 265.003, 292.055, 295.02, 295.07, 295.187, 295.188, 296.02, 296.08, 296.33, 296.36, 409.1664, 548.06, 943.17, and 1009.26, F.S.

[13] U.S. Department of Veterans Affairs (VA), National Center for Veterans Analysis and Statistics, *VetPop2020 by State, Age Group, Gender, 2020-2050*, available at https://www.va.gov/vetdata/veteran_population.asp (last visited Jan. 25, 2024). The Veteran Population Projection Model 2020 (VetPop2020) provides an official veteran population projection from the U.S. Department of Veterans Affairs.

[14] *VA and Marijuana – What Veterans need to know*, U.S. Department of Veterans Affairs, https://www.publichealth.va.gov/marijuana.asp (last visited on January 26, 2024).

- VA clinicians may only prescribe medications that have been approved by the U.S. Food and Drug Administration (FDA) for medical use. At present most products containing tetrahydrocannabinol (THC), cannabidiol (CBD), or other cannabinoids are not approved for this purpose by the FDA.
- VA clinicians may not complete paperwork/forms required for Veteran patients to participate in state-approved marijuana programs.
- VA pharmacies may not fill prescriptions for medical marijuana.
- VA will not pay for medical marijuana prescriptions from any source.
- VA scientists may conduct research on marijuana benefits and risks, and potential for abuse, under regulatory approval.
- The use or possession of marijuana is prohibited at all VA medical centers, locations and grounds. When you are on VA grounds it is federal law that is in force, not the laws of the state.
- Veterans who are VA employees are subject to drug testing under the terms of employment.

The number of veterans who hold active medical marijuana use registry identification cards is unknown.

Effect of the Bill

HB 1435 exempts veterans from the annual medical marijuana use registry identification card fee. The bill requires individuals to prove their status as a veteran by providing any of the following documents to OMMU:

- A DD Form 214, issued by the United States Department of Defense;
- A veteran health identification card, issued by the United States Department of Veterans Affairs; or
- A veteran identification card, issued by the United States Department of Veterans Affairs pursuant to the Veterans Identification Card Act of 2015, Pub. L. No. 114-31.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.986, F.S., relating to medical use of marijuana.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has an indeterminate, negative fiscal impact on DOH. Currently, there are 871,459 qualified patients with active medical marijuana use registry identification cards who must pay $75 annually to retain an active identification card. The number of veterans who hold active medical marijuana use registry identification cards is unknown however, DOH will no longer be able to collect fees from these patients.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will have a positive fiscal impact on veterans who will not be required to pay the annual $75 identification card fee.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rulemaking authority to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to medical marijuana use registry identification cards for veterans; amending s. 381.986, F.S.; providing a waiver of the issuance and renewal fees for a medical marijuana use registry identification card for veterans; providing requirements for proof of identification; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (f) is added to subsection (7) of section 381.986, Florida Statutes, to read:

381.986 Medical use of marijuana.—

(7) IDENTIFICATION CARDS.—

(f) A qualified patient who is a veteran, as defined in s. 1.01(14), is not required to pay the fee for the issuance or renewal of a medical marijuana use registry identification card. A qualified patient must provide the department with a copy of one of the following as proof of identification:

1. A DD Form 214, issued by the United States Department of Defense;

2. A veteran health identification card, issued by the United States Department of Veterans Affairs; or

3. A veteran identification card, issued by the United

States Department of Veterans Affairs pursuant to the Veterans Identification Card Act of 2015, Pub. L. No. 114-31.

Section 2. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	___ (Y/N)
ADOPTED AS AMENDED	___ (Y/N)
ADOPTED W/O OBJECTION	___ (Y/N)
FAILED TO ADOPT	___ (Y/N)
WITHDRAWN	___ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Valdés offered the following:

Amendment

Remove everything after the enacting clause and insert:

Section 1. Paragraph (f) is added to subsection (7) of section 381.986, Florida Statutes, is amended to read:

381.986 Medical use of marijuana.—

(7) IDENTIFICATION CARDS.—

(f) The department may not charge a fee for the issuance, replacement, or renewal of an identification card for a service-disabled veteran, as defined in s. 295.187(3), if the veteran's DD-214 form is included with the application for the identification card.

Section 2. This act shall take effect July 1, 2024.

PCS for HB 349

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 349 Sickle Cell Management and Treatment Education for Physicians
SPONSOR(S): Healthcare Regulation Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Healthcare Regulation Subcommittee		Osborne	McElroy

SUMMARY ANALYSIS

Sickle cell disease (SCD) is the most common inherited blood disorder in the United States, affecting approximately 100,000 Americans. SCD affects mostly, but not exclusively, Americans of African ancestry. SCD is a group of inherited disorders in which abnormal hemoglobin cause red blood cells to buckle into the iconic sickle shape; the deformed red blood cells damage blood vessels and over time contribute to a cascade of negative health effects beginning in infancy, such as intense vaso-occlusive pain episodes, strokes, organ failure, and recurrent infections. The severity of complications generally worsens as people age, but treatment and prevention strategies can mitigate complications and lengthen the lives of people with SCD.

Treatment for SCD has improved significantly in recent decades. Appropriate pharmaceutical treatments and evidence-based management protocols have the capacity to significantly improve the quality of life for people with SCD. In spite of the improvements in treatments for SCD, there significant underutilization among patients, due in part to gaps in understanding of the disease and its treatments among health care practitioners.

PCS for HB 349 requires specified health care practitioners to complete two hours of continuing education on the subject of sickle care disease management as a part of every second biennial licensure or certification renewal. The bill specifies that the course shall consist of education specific to SCD, including evidence-based treatment protocols for patients of all ages, continuing patient and family education, periodic comprehensive health evaluations and other disease-specific health maintenance services, psychosocial care, genetic counseling, and pain management.

The Board of Medicine, the Board of Osteopathic Medicine, and the Board of Nursing are responsible for implementing the provisions of the bill and approving appropriate continuing education courses. The bill authorizes each board to adopt rules to implement the provisions of the bill.

The continuing education course required under the bill may count toward a licensee's total number of continuing education requirements for professionals required to complete 30 or more hours of continuing education biennially. The bill allows a professional holding two or more licenses subject to the requirements of the bill to satisfy such requirement through the completion of one board-approved course. Failure to comply with the requirements of the bill constitute grounds for disciplinary action.

The bill has an indeterminant, negative fiscal impact on state government, and no fiscal impact on local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Sickle Cell Disease

Sickle cell disease (SCD) is the most common inherited blood disorder in the United States, affecting approximately 100,000 Americans.[1] SCD affects mostly, but not exclusively, Americans of African ancestry.[2] SCD is a group of inherited disorders in which abnormal hemoglobin cause red blood cells to buckle into the iconic sickle shape; the deformed red blood cells damage blood vessels and over time contribute to a cascade of negative health effects beginning in infancy, such as intense vaso-occlusive pain episodes, strokes, organ failure, and recurrent infections.[3] The severity of complications generally worsens as people age, but treatment and prevention strategies can mitigate complications and lengthen the lives of people with SCD.[4]

The nature of SCD inherently leads to a greater use of health care services compared to the general population, but gaps in access to appropriate care are common and lead to unmitigated health crises and a greater consumption of costly emergency medical services.[5] Historically SCD was associated with childhood mortality, however, more than 90 percent of those living with the disease are expected to survive into adulthood today.[6] As the system of care for SCD has developed with a focus on pediatric patients, children with SCD are more likely to receive well-managed preventative care through specialized pediatric programs. Patients aging out of pediatric care and transitioning into adult care are less likely to have access to consistent and appropriate SCD care, and as such have higher rates of emergency department reliance than other age groups.[7] Roughly 60% of individuals with SCD in the US today are adults, but the life expectancy of individuals with SCD remains approximately 22 years shorter than the general population.[8]

Management of SCD

SCD management primarily focuses on treating and preventing complications caused by the disease such as acute pain episodes, infection, stroke, vision loss, and severe anemia. The most well-researched treatments for SCD relate to mitigating a person's risk of infection and stroke. Daily oral penicillin is the standard of care for children with SCD because chronic damage to the spleen increases

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[1] National Heart, Lung, and Blood Institute, *What is Sickle Cell Disease?* Available at https://www.nhlbi.nih.gov/health/sickle-cell-disease (last visited January 30, 2024).
[2] Centers for Disease Control and Prevention, *Data & Statistics on Sickle Cell Disease*. Available at https://www.cdc.gov/ncbddd/sicklecell/data.html (last visited January 30, 2024).
[3] Centers for Disease Control and Prevention, *What is Sickle Cell Disease?* Available at https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited January 24, 2024). See also, AHCA (2023) *Florida Medicaid Study of Enrollees with Sickle Cell Disease*. Available at https://ahca.myflorida.com/content/download/20771/file/Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (last visited January 24, 2024).
[4] Centers for Disease Control and Prevention, *Complications of Sickle Cell Disease*. Available at https://www.cdc.gov/ncbddd/sicklecell/complications.html (last visited January 24, 2024).
[5] DiMartino, L. D., Baumann, A. A., Hsu, L. L., Kanter, J., Gordeuk, V. R., Glassberg, J., Treadwell, M. J., Melvin, C. L., Telfair, J., Klesges, L. M., King, A., Wun, T., Shah, N., Gibson, R. W., Hankins, J. S., & Sickle Cell Disease Implementation Consortium (2018). *The sickle cell disease implementation consortium: Translating evidence-based guidelines into practice for sickle cell disease.* American journal of hematology, 93(12), E391–E395. https://doi.org/10.1002/ajh.25282. *See also*, Brousseau, D.C., Owens, P.L., Mosso, A.L., Panepinto, J.A., Steiner, C.A. (2010). *Acute Care Utilization and Rehospitalizations for Sickle Cell Disease*. JAMA. 2010;303(13):1288–1294. doi:10.1001/jama.2010.378
[6] *Id*.
[7] Blinder, M. A., Duh, M. S., Sasane, M., Trahey, A., Paley, C., & Vekeman, F. (2015). *Age-Related Emergency Department Reliance in Patients with Sickle Cell Disease*. The Journal of emergency medicine, 49(4), 513–522.e1. https://doi.org/10.1016/j.jemermed.2014.12.080
[8] Lubeck D, Agodoa I, Bhakta N, et al. (2019) *Estimated Life Expectancy and Income of Patients With Sickle Cell Disease Compared With Those Without Sickle Cell Disease*. JAMA Netw Open. 2019;2(11):e1915374. doi:10.1001/jamanetworkopen.2019.15374. Available at https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2755485 (last visited January 30, 2024).

the risk of life-threatening pneumococcal bacterial infection.[9] For reducing stroke risk, blood transfusions are commonly used in conjunction with routine screening using a specialized ultrasound device which is able to detect elevated stroke risk.[10] Blood transfusions may be used to treat acute episodes of elevated stroke risk, or through chronic transfusion therapy which reduces a person's overall stroke risk as well as preventing painful vaso-occlusive events.[11] Chronic transfusion therapy has been shown to improve health-related quality of life in children with SCD.[12] There are, however, risks associated with frequent blood transfusions and chronic transfusion therapy can be logistically and financially difficult for caregivers to manage.[13]

In addition to daily oral penicillin and routine screening to monitor stroke risk in children, there are other pharmaceutical treatments available to manage the symptoms of SCD, reduce the long-term health impacts of the disease, and improve quality of life for children and adults with SCD.

Hydroxyurea is an oral medication taken once daily which has been proven to be effective at reducing a person's pain episodes, mitigating stroke risk, and preventing organ damage.[14] Hydroxyurea is generally safe for both children and adults and is recommended for patients with certain forms of SCD experiencing "frequent pain episodes" or acute chest syndrome.[15]

Opioids are commonly used to treat the severe acute pain that results from vaso-occlusive episodes. Opioids are not recommended for treatment of the chronic pain that is associated with SCD due to the significant risks of overdose and addiction associated with frequent opioid use. Opioids are, however, very effective for managing acute severe pain in acute settings and as such the National Heart Lung and Blood Institute recommends rapid initiation of opioids for patients visiting the emergency department for a vaso-occlusive pain episode.[16]

More recent pharmaceutical developments for the treatment of SCD include L-glutamine, Voxelotor, and Crizanlizumab. L-glutamine in an essential amino acid which was approved by the FDA in 2017 for the treatment of SCD in adults and children over five years of age. The mechanism of action of L-glutamine is not well understood, however, it has been shown to reduce a patient's number of sickle cell crisis episodes.[17] Voxelotor and Crizanlizumab are two disease modifying drugs approved by the FDA in 2019. The drugs may be beneficial for different subgroups of SCD patients for whom other treatments have proven insufficient or ineffective. Voxelotor and Crizanlizumab act through different mechanisms, but both mitigate the harmful effects of damaged red blood cells in the body. There is ongoing research into their impact on other SCD morbidities.[18]

Curative Treatments for SCD

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[9] AHCA (2023) *Florida Medicaid Study of Enrollees with Sickle Cell Disease*. Available at https://ahca.myflorida.com/content/download/20771/file/Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (last visited January 24, 2024). Amoxicillin may also be prescribed for this purpose. In patients with a known or suspected penicillin allergy, erythromycin is prescribed.

[10] Runge, A., Brazel, D., Pakbaz, Z. (2022). *Stroke in Sickle Cell Disease and the Promise of Recent Disease Modifying Agents*. Journal of the Neurological Sciences. http://doi.org/10.1016/j.jns.2022.120412

[11] Brandow, A.M., Panepinto, J.A. (2010). *Hydroxyurea Use in Sickle Cell Disease: The Battle with Low Prescription Rates, Poor Patient Compliance, and Fears of Toxicities*. Expert Reviews: Hematology. DOI: 10.1586/EHM.10.22

[12] Beverung, L.M., Strouse, J.J., Hulbert, M.L. (2015) *Health-related Quality of Life in Children with Sickle Cell Anemia: Impact of Blood Transfusion Therapy*. American Journal of Hematology. http://doi.org/10/1002/ajh.2387

[13] *Supra*, note 10.

[14] *Id.*

[15] U.S. Department of Health and Human Services, National Heart, Lung, and Blood Institute. *Evidence-Based Management of Sickle Cell Disease: Expert Panel Report* (2014). Available at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease (last visited January 31, 2024).

[16] *Id. See also*, Smeltzer, M.P., Howell, K.E., Treadwell, M. (2021). *Identifying barriers to evidence-based care for sickle cell disease: results from the Sickle Cell Disease Implementation Consortium cross-sectional survey of healthcare providers in the USA*. BMJ Open 2021. DOI: 10.1136/bmjopen-2021-050880

[17] Quinn C. T. (2018). *l-Glutamine for sickle cell anemia: more questions than answers*. Blood, 132(7), 689–693. https://doi.org/10.1182/blood-2018-03-834440. *See also*, Ballas S. K. (2020). *The Evolving Pharmacotherapeutic Landscape for the Treatment of Sickle Cell Disease*. Mediterranean journal of hematology and infectious diseases, 12(1), e2020010. https://doi.org/10.4084/MJHID.2020.010

[18] *Supra*, note 10.

On December 8, 2023, the FDA approved the first two gene therapies, Casgevy and Lyfgenia, to treat patients with SCD. The products are cell-based gene therapies approved for the treatment of SCD in patients 12 years of age or older. Both products are made from the patients' own blood stem cells, which are modified, and are given back as a one-time, single-dose infusion as part of a hematopoietic (blood) stem cell transplant. Prior to treatment, a patients' own stem cells are collected, and then the patient must undergo myeloablative conditioning (high-dose chemotherapy), a process that removes cells from the bone marrow so they can be replaced with the modified cells.[19]

The FDA-approved gene therapies have not reached full market availability, but the costs are anticipated to be as high as $2 to million per patient.[20] It is yet to be determined how insurance companies or Medicaid will cover the treatment.[21]

Prior to the approval of these gene therapy treatments, the only treatment for SCD with curative potential was a matched/related hematopoietic stem cell transplant (HSCT). HSCT has been shown to be highly effective as a cure, though outcomes are more favorable when the transplant is performed before age 16 and with a matched sibling donor.[22] While highly curative, HSCT poses significant risks including transplant rejection that can result in the patient's death.[23] The procedure is infrequently performed due to the high cost,[24] the limited number of capable transplant centers, the strenuous preparation regimen and significant risks,[25] and the need for a genetically matched donor.[26]

Barriers to Care for SCD

While SCD is the most common inherited blood disorder in the US and is often diagnosed at birth through newborn screening programs,[27] patients with SCD often experience significant barriers to accessing appropriate care. Recent decades have brought major scientific advancements in understanding the biological mechanisms of SCD, the development of new pharmaceutical treatments, the establishment of evidence-based treatment protocols, and methods for mitigating the risk of catastrophic complications.[28] Collectively, these advancements provide the means for significantly improving the quality of life for many patients with SCD; however, few of these interventions are utilized to their full potential.

Barriers to care include lack of insurance, transportation needs, and provider inexperience and lack of knowledge about SCD. There is a limited number of knowledgeable health care professionals with expertise in the management of SCD, and mistrust among patients and bias among providers continue to affect access to and quality of care.[29]

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[19] US Food & Drug Administration, *FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease* (2023). Available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease (last visited January 30, 2024).
[20] National Heart, Lung, and Blood Institute. *FDA approval of gene therapies for sickle cell disease: Q&A with NHLBI Director Dr. Gary Gibbons and NHLBI's Division of Blood Diseases and Resources Director Dr. Julie Panepinto* (2023). Available at https://www.nhlbi.nih.gov/news/2023/fda-approval-gene-therapies-sickle-cell-disease-dr-gibbons-dr-panepinto (last visited January 30, 2024).
[21] MacMillan, C., *Casgevy and Lyfgenia: Two Gene Therapies Approved for Sickle Cell Disease*. (2023). Yale Medicine. Available at https://www.yalemedicine.org/news/gene-therapies-sickle-cell-disease (last visited January 30, 2023).
[22] Gluckman, E., Cappelli, B., Bernaudin, F., et al. (2017). *Sickle cell disease: an international survey of results of HLA-identical sibling hematopoietic stem cell transplantation*. Blood, 129(11), 1548–1556. https://doi.org/10.1182/blood-2016-10-745711
[23] Ashorobi D, Bhatt R. *Bone Marrow Transplantation in Sickle Cell Disease*. (2022). In: StatPearls. Treasure Island (FL): StatPearls Publishing. Available at https://www.ncbi.nlm.nih.gov/books/NBK538515/ (last visited January 31, 2024).
[24] *Supra*, note 15. HSCT is estimated to cost approximately $1 million to $2 million per person.
[25] *Supra*, note 15.
[26] Salcedo, J., Bulovic, J., & Young, C. (2021). *Cost-effectiveness of a Hypothetical Cell or Gene Therapy Cure for Sickle Cell Disease.* Scientific Reports. https://doi.org/10.1038/s41598-021-90405-1
[27] Centers for Disease Control and Prevention. *Newborn Screening (NBS) Data* (2023). Available at https://www.cdc.gov/ncbddd/hemoglobinopathies/scdc-state-data/newborn-screening/index.html#:~:text=Newborn%20screening%20(NBS)%20for%20sickle,SCD%20living%20in%20a%20state. (last visited January 20, 2024).
[28] American Society of Hematology. *ASH Sickle Cell Disease Initiative: Sickle Cell Disease Timeline*. Available at https://www.hematology.org/advocacy/sickle-cell-disease-initiative/scd-timeline (last visited January 30, 2024).
[29] Sickle Cell Disease Coalition, State of Sickle Cell Disease: 2020 Report Card (2020). Available at http://www.scdcoalition.org/pdfs/SCD%20Report%20Card%202020.pdf (last visited January 31, 2024).

Access to adequate care is especially challenging for young adults transitioning from pediatric to adult care settings.[30] Lack of health insurance and underinsurance among adults with SCD leads to difficulty accessing care and an overutilization of emergency health services. SCD care in emergency settings presents additional challenges. Educational gaps and biases among providers, staff, and patients create barriers to communication and trust, and erode the provider–patient relationship, which can result in inadequate or inappropriate treatment of patients.[31]

Florida's SCD Medicaid Population

Pursuant to directives in the 2022 General Appropriations Act, the Agency for Health Care Administration (AHCA) published a report in February 2023 assessing Florida's population of Medicaid enrollees with SCD, as well as the utilization of specific health care services by this population.[32] Analyzing data from 2018 through 2021, the report found that Florida's rate of Medicaid enrollees with SCD was twice that of the national average,[33] with approximately 7,328 Medicaid enrollees with SCD per year. Florida's Medicaid SCD population was predominantly female (58%), young (median age 18), and Black (63%). Nearly all of the Medicaid SCD population was treated by a physician at least once during the study period; 85% were evaluated or treated in an outpatient clinic setting, 61% were treated in an ER at least once, and 52% were admitted for inpatient care in a hospital. Individuals treated in an ER had an average of 4.5 visits to the ER during the four-year study period.

The report showed that routine screenings and preventative treatments were broadly underutilized by the Medicaid SCD population. Only 41% of children in the Medicaid SCD population had at least one transcranial Doppler ultrasound to screen for stroke risk during the four-year study period; this is significantly less than the recommended annual screening for children with SCD.[34] Data on blood transfusions, which are commonly used to reduce stroke risk when elevated risk is detected with an ultrasound, were not included in the AHCA report. Penicillin was the most commonly prescribed medication, with 58% of eligible individuals receiving the drug, but there remains a persistent gap between use and recommended care. Other medications which mitigate SCD complications were prescribed with even less frequency. Hydroxyurea and L-glutamine, both of which are on Florida's Medicaid Preferred Drug List (PDL), were prescribed to only 22% and 2% of eligible SCD Medicaid patients respectively. While Hydroxyurea is on the PDL, AHCA cites high-cost as a potential barrier to the utilization of this drug. The newer disease-modifying drugs, Voxelotor and Crizanlizumab are not on the PDL and were each prescribed to less than 1% of the eligible SCD Medicaid population.

Health Care Professional Licensure

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.[35] The MQA works in conjunction with 22 professional boards and four councils to license and regulate seven types of health care facilities and more than 40 health care professions. Every profession is regulated by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA, as well as a profession- or field-specific practice act

[30] Hemker, B., Brouseau, D., Yan, K., Hoffmann, R., & Panepinto. *When Children with Sickle Cell Disease Become Adults: Lack of Outpatient Care Leads to Increased Use of the Emergency Department* (2011). American Journal of Hematology. 86:10, 863-865. https://doi.org/10.1002/ajh.22106

[31] Glassberg, G., *Improving Emergency Department-Based Care of Sickle Cell Pain* (2017). Hematology. American Society of Hematology. Education Program, 2017(1), 412–417. https://doi.org/10.1182/asheducation-2017.1.412

[32] AHCA (2023) *Florida Medicaid Study of Enrollees with Sickle Cell Disease*. Available at https://ahca.myflorida.com/content/download/20771/file/Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (last visited January 30, 2024).

[33] Centers for Medicare and Medicaid Services (2021), *Medicaid and CHIP Sickle Cell Disease Report, T-MSIS Analytic Files (TAF) 2017*. Available at https://www.medicaid.gov/medicaid/quality-of-care/downloads/scd-rpt-jan-2021.pdf (last visited January 31, 2024).

[34] *Supra*, note 15.

[35] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, mental health counselors, and psychotherapists, among others.

which outlines requirements and standards that vary by profession and establishes the individual professional boards.

A professional board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.[36] Boards are responsible for approving or denying applications for licensure,[37] establishing continuing medical education requirements,[38] and are involved in disciplinary hearings.[39]

Continuing Education Requirements

General continuing education requirements for many health care practitioners, including those practitioners regulated by the Board of Medicine, the Board of Osteopathic Medicine, the Board of Chiropractic Medicine, and the Board of Podiatric Medicine, are established under s. 456.013, F.S. As a condition of their biennial licensure renewal, these professions are required to periodically demonstrate their professional competency through the completion at least 40 hours of continuing education ever two years.[40]

Health care practitioners regulated by the Board of Nursing, specifically licensed practical nurses and registered nurses, and advanced practice registered nurses, may be required by the board to complete up to 30 hours of continuing education as a condition for biennial licensure renewal.[41]

In addition to the general continuing education requirements, current law requires some health care professions to complete continuing education courses covering specific subjects as a condition for licensure or certification renewal. The following subjects are required continuing education for specified health care practitioners:

- Human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS);[42]
- Human trafficking;[43] and
- Domestic violence.[44]

It is the respective professional board's responsibility to approve specific continuing education courses that fulfill the statutory requirements. Failure of a licensee to comply with the continuing education requirements constitute grounds for disciplinary action.[45] In addition to discipline by the board, the licensee is required to complete the course.[46]

Effect of the Bill

PCS for HB 349 requires health care practitioners licensed or certified under chapters 458, 459, and 464, F.S., to complete two hours of continuing education on the subject of sickle care disease management as a part of every second biennial licensure or certification renewal. The health care practitioners required to complete this continuing education course includes allopathic physicians,

[36] S. 456.001(1), F.S.
[37] S. 456.013, F.S.
[38] *Id*.
[39] S. 456.072, F.S
[40] S. 456.013(6), F.S.
[41] S. 464.013, F.S.; Advanced practice registered nurses are required to complete at least three hours of continuing education on the safe and effective prescription of controlled substances as part of the 30-hour maximum.
[42] S. 456.033, F.S.; upon first licensure renewal, a one-hour course is required for health care practitioners licensed under ch. 457, ch. 458, ch. 459, ch. 460, ch. 461, ch. 463, part I of ch. 464, ch. 465, ch. 466, part II, part III, part V, or part X of ch. 468, and ch. 486, F.S.
[43] S. 456.0341, F.S.; A one-hour course is required for health care practitioners licensed under ch. 457, ch. 458, ch. 459, ch. 460, ch. 461, ch. 463, ch. 465, ch. 466, part II, part III, part V, or part X of ch. 468, ch. 480, and ch. 486, F.S.; *See also*, s. 464.013, F.S., licensed professional nurses, registered nurses, and advanced practice registered nurses are required to complete a two-hour course for every biennial licensure renewal.
[44] S. 456.031, F.S.; A two-hour course is required as part of every third biennial licensure or certification renewal for health care practitioners licensed under ch. 458, ch. 459, part I of ch. 464, ch. 466, ch. 467, ch. 490, and ch. 491, F.S.
[45] S. 456.072, F.S.
[46] Ss. 456.031 and 456.033, F.S.

osteopathic physicians, physician assistants, anesthesiologist assistance, licensed practical nurses, registered nurses, and advanced practice registered nurses.

The required continuing education course may count toward a licensee's total number of required continuing education hours for those professionals required to complete 30 or more hours of continuing education biennially. The bill allows a professional holding two or more licenses subject to the requirements of the bill to satisfy such requirement through the completion of one board-approved course. Failure to comply with the requirements of the bill constitute grounds for disciplinary action by the appropriate professional board. In addition to discipline by the board, the bill requires that the licensee complete the required course.

The bill specifies that the course shall consist of education specific to SCD, including evidence-based treatment protocols for patients of all ages, continuing patient and family education, periodic comprehensive health evaluations and other disease-specific health maintenance services, psychosocial care, genetic counseling, and pain management.

The Board of Medicine, the Board of Osteopathic Medicine, and the Board of Nursing are responsible for implementing the provisions of the bill and approving appropriate continuing education courses. The bill authorizes each board to adopt rules to implement the provisions of the bill.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0311, F.S., relating to requirement for instruction on sickle cell disease.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has an insignificant, negative fiscal impact on DOH associated with rulemaking necessary to implement the provisions of the bill, which can be absorbed with in existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to sickle cell care management and treatment education; creating s. 456.0311, F.S.; requiring specified continuing education courses for licensure renewal for specified health care professions; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.0311, Florida Statutes, is created to read:

456.0311 Requirement for instruction on sickle cell disease.—

(1)(a) The appropriate board shall require each person licensed or certified under chapter 458, chapter 459, or part I of chapter 464 to complete a 2-hour continuing education course, approved by the board, on sickle cell disease care management as part of every second biennial licensure or certification renewal. The course shall consist of education specific to sickle cell disease and sickle cell trait including, but not limited to, evidence-based treatment protocols for patients of all ages, continuing patient and family education, periodic comprehensive evaluations and other disease-specific health maintenance services, psychosocial care, genetic counseling, and pain management.

(b) Each such licensee or certificateholder shall submit confirmation of having completed such course, on a form provided by the board, when submitting fees for every second biennial renewal.

(c) The board may approve additional equivalent courses that may be used to satisfy the requirements of paragraph (a). Each licensing board that requires a licensee to complete an educational course pursuant to this section may include the hour required for completion of the course in the total hours of continuing education required by law for such profession unless the continuing education requirements for such profession consist of fewer than 30 hours biennially.

(d) Any person holding two or more licenses subject to the provisions of this section shall be permitted to show proof of having taken one board-approved course to satisfy the requirements of paragraph (a), for purposes of relicensure or recertification for additional licenses.

(e) Failure to comply with the requirements of this section shall constitute grounds for disciplinary action under each respective practice act and under s. 456.072(1)(k). In addition to discipline by the board, the licensee shall be required to complete such course.

(2) Each board may adopt rules to carry out the provisions of this section.

Section 2. This act shall take effect July 1, 2024.